



DOCUMENT REVIEW AND REVISION HISTORY

General Information	
Document Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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Review Order	Dates	Revision		
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2	June 2015	2		
3	January 2016	3		
4	December 2018	4		
5	September 2019	5		
6	June 2022	6		
7	March 2024 December 2024	7		
			Relocation of SOPs: - SOPs pertaining to Types of Review have been moved to SOP 3. - SOPs governing the Management of Initial Submissions are now included in SOP 2. Additions in Alignment with PHREB and FERCAP Recommendations: - SOP 2.2: Management of Single Joint Research Ethics Board (SJREB) Reviews - SOP 2.3: Withdrawal of Submission - SOP 3.4: Review Process for SJREB Submissions - SOP 3.5: Preparation of Notice of Action (NOA) or Ethical Clearance (EC) - SOP 3.8: Management of Appeals of Committee Decisions - SOP 3.9: Management of Queries and Complaints Streamlining and Merging of SOPs: - SOP 3.2: Preliminary Review by SLMC-IERC Members has been incorporated into SOP 2.1. - SOP 5.3: Preparation and Conduct of Meeting has been incorporated into SOP 3.3. - SOP 5.7: Electronic Submission, Review, and Documentation has been integrated into all affected SOPs. Removal of SOP 2.5: Review of Protocols for Regulatory (PFDA) Approvals as recommended by PHREB and FERCAP. Revised SOP Titles: - SOP 2.6: Review of Clinical Trials Related to Public Health Emergencies (formerly Review of Clinical Trials Related to Pandemic Diseases or Disease Outbreaks) - SOP 6.1: Writing and Revising SOPs (formerly Preparation and Amendment of SOPs) - SOP 6.2: Guidelines in Preparing SOPs (formerly Preparation Guidelines in SOPs) - Replacement of Flowcharts with Workflows as recommended by PHREB and FERCAP - Updated References Section	

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1. INTRODUCTION

Research Ethics Committees (RECs) play a crucial role in safeguarding human participants in research. Hence, institutions must develop policies and procedures regarding research and ensure the establishment and adequate support of RECs in line with established standards. RECs are expected to possess the capacity to conduct comprehensive and impartial evaluations and oversight of all research involving human participants. They are required to implement SOPs to ensure that REC operations are transparent, accountable, proficient, timely, and uniform.

This SOP outlines the steps involved in evaluating human subject research protocols against relevant ethical principles, laws, regulations, and standards established by local and international regulatory and accrediting bodies related to research. It provides guidance to SLMC-IERC staff to ensure a thorough and consistent evaluation process. Specifically, it details the procedures for managing all submissions, records, and communications and for maintaining a database. Additionally, the SOP provides guidance to researchers, sponsors, clinical research organizations, and other stakeholders to ensure they understand the expectations and requirements for ethical compliance in their research activities.

This SOP is a dynamic document that undergoes periodic reviews and revisions to address emerging issues and incorporate new regulations and guidelines as they are released. The SOP ensures its ongoing relevance and effectiveness by staying current through this iterative process.

The SLMC-IERC encourages feedback and welcomes questions from a variety of research stakeholders and users of this SOP. Those interested in providing input or interacting with the SLMC-IERC may contact ethicsreview@stlukes.com.ph.

2. OBJECTIVE

This document establishes the Standard Operating Procedure (SOP) manual of the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC). For brevity, the manual will be referred to as the SOP throughout this document.

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3. RESPONSIBILITIES

RESEARCH STRUCTURE AT ST. LUKE'S MEDICAL CENTER

3.1. RESEARCH AND BIOTECHNOLOGY GROUP

The **Head of Research and Biotechnology (R&B) Group** at St. Luke's Medical Center (SLMC) holds the responsibility for overseeing all research activities within the Medical Center, SLMC College of Medicine-WHQM (SLMCCM-WHQM), and St. Luke's Extension Clinic (SLEC). This oversight ensures that studies are conducted ethically and in compliance with applicable laws, regulations, requirements, and standards set by local and international regulatory and accrediting bodies related to research.

The **R&B Center for Clinical Research's (CCR) Office of Research Integrity (ORI)** provides support for the structure and operational needs of the SLMC-IERC. It conducts an annual review of all research review processes and implements education and training activities for IERC members, staff, and researchers at SLMC. It ensures compliance with local laws and regulations by maintaining accreditation from the Philippine Health Research Ethics Board (PHREB) and recognition from the WHO SIDCER Forum for Ethics Review Committees in Asia and the Western Pacific (FERCAP).

The **St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC)** is responsible for reviewing protocols of all sponsor-initiated clinical trials (SiT) and investigator-initiated research studies involving human subjects (IiT). This review ensures adherence to ethical standards outlined in the International Conference of Harmonization Guidelines for Good Clinical Practice (ICH-GCP), the Philippine Health Research Ethics Board (PHREB), and other relevant standards and guidelines on research ethics (e.g., Declaration of Helsinki, Philippines National Ethical Guidelines for Research Involving Human Participants).

3.2. THE ST. LUKE'S MEDICAL CENTER INSTITUTIONAL ETHICS REVIEW COMMITTEE

This section provides an overview of the SLMC-IERC and its evolution over time to meet the challenges of safeguarding the dignity, rights, safety, and welfare of all individuals involved in research activities.

The primary objective of the SLMC-IERC is to safeguard the dignity, rights, safety, and welfare of all individuals involved or potentially involved in research activities. Meeting this objective

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requires maintaining independence from political, institutional, professional, or commercial influences in its structure, procedures, and decision-making processes.

The SLMC-IERC reflects the guidelines set forth by Philippine institutions regarding biomedical, behavioral, and social research. As mandated by SLMC, the SLMC-IERC functions as an institutional REC, ensuring an impartial, proficient, and prompt ethical evaluation of proposed studies within the institution.

The SLMC-IERC has a functional structure composed of the Chair, Vice Chair, Member-Secretary, Members (Regular and Alternate), and Independent Consultants, under the organizational structure below, which shows its location within the institutional organizational structure.

Table of Organization:

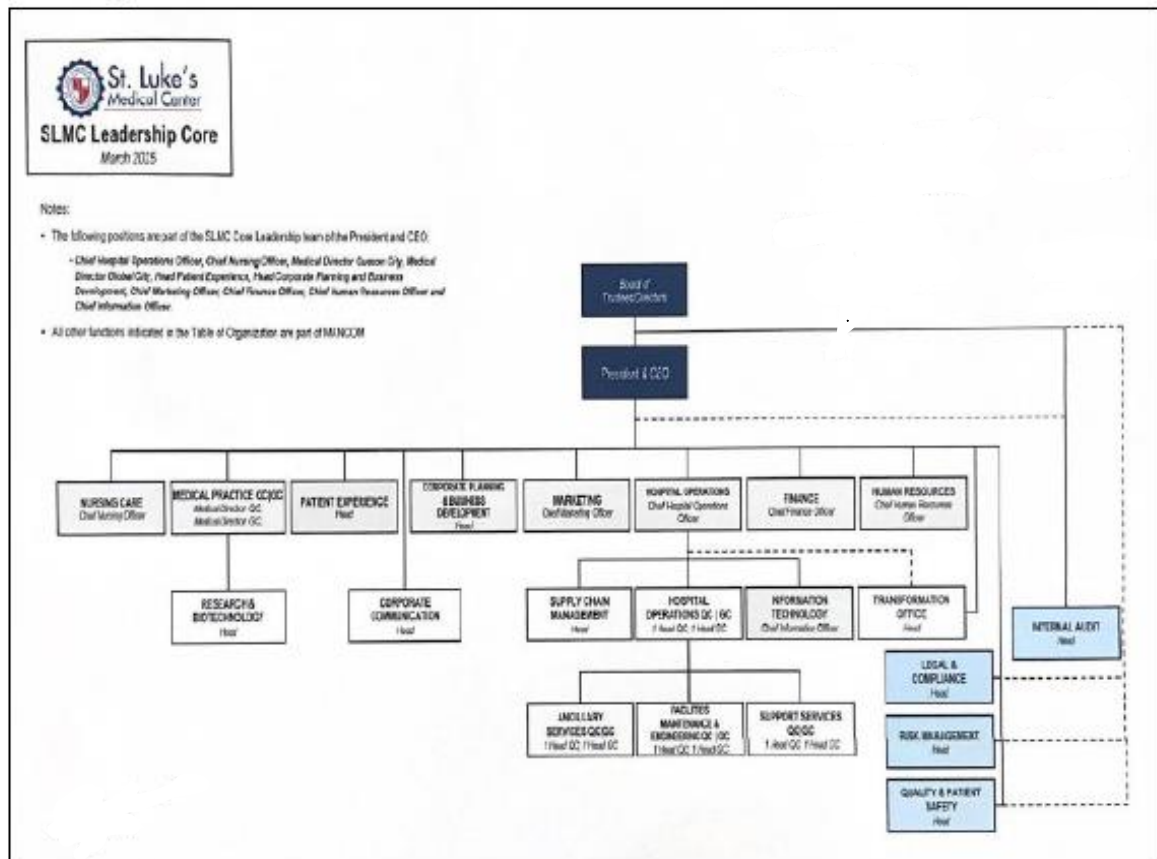


Figure 1: SLMC Table of Organization



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3.3. ACCREDITATION STANDARDS

The SLMC-IERC is responsible for the review of the protocols of all sponsor-initiated clinical trials (SiT) and investigator-initiated research studies involving human subjects (IiT) in SLMC, SLMCCM-WHQM, and SLEC. The current structure of SLMC-IERC was established in 2011 and registered as an ethics review committee (Registration Number 07-033) in the Philippine Health Ethics Review Board (PHREB) system. In 2012, it was granted recognition by the Strategic Initiative for Developing Capacity in Ethical Review - Forum for Ethical Review Committees in Asia and the Western Pacific (SIDCER-FERCAP); renewed in 2015 and 2019. It acquired its first PHREB Level 3 Accreditation in 2013; renewed in 2016, 2019 and 2025.

The recent reaccreditation of SLMC by the Joint Commission International (JCI) as an academic medical center has heightened the challenge for the SLMC-IERC. Aligned with the title 'academic medical center' is the recognition of research as an inevitable part of the mission and identity of SLMC. In this mandated research environment, the SLMC-IERC is expected to be vigilant and reinforce its commitment to upholding the integrity and protection of human participants.

In 2019, motivated by recommendations from PHREB, FERCAP, and JCI, the SLMC-IERC implemented significant SOP revisions, refining full-board reviews, site visits, and monitoring protocols to ensure robust ethics review processes.

In 2021, the global COVID-19 pandemic prompted the inclusion of new guidelines addressing clinical trials related to public health emergencies, ensuring timely and ethical research oversight.

The 2025 edition further strengthens the ethics review framework by incorporating additional updates based on PHREB recommendations, such as the management and evaluation process for Single Joint Research Ethics Board (SJREB) submissions, procedures for withdrawal of submissions, management of appeals on committee decisions and guidelines for managing queries and complaints. These updates enhance procedural clarity, ensuring SLMC-IERC operations remain aligned with evolving national and international ethical standards for high-quality research oversight.

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4. THE SLMC-IERC STANDARD OPERATING PROCEDURES (SOP) MANUAL 2025

The SLMC-IERC SOP MANUAL 2025 edition documents the current ethics review processes within the SLMC-IERC. It reflects the recommendations following periodic internal review and the PHREB accreditation and FERCAP visit in February 2024. These recommendations describe external conditions steadily confronting ethics review committees, including constantly emerging technologies and scientific advancements in medicine, the ever-changing complexity of diseases, especially the rise of new and resistant infectious organisms, and the recent COVID-19 global pandemic, leading to stringent regulations from government and regulatory agencies.

This 2025 edition was prepared in accordance with international, national, and institutional guidelines, namely:

- National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022
- Philippine National Health Research System Act of 2013
- Declaration of Helsinki 2024
- International Ethical Guidelines for Health-related Research Involving Humans 2016, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)
- WHO standards and operational guidance for ethics review of health-related research with human participants, 2011
- ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2) 2016
- Data Privacy Act of 2012

Additionally, the term "(bio)medical research" was transitioned to "health-related research." This change was motivated by the recognition that the former was too restrictive. Biomedical research, as a term, fell short of encompassing studies involving health-related data, which was a limitation. The SLMC-IERC acknowledged the need for a more inclusive approach to better reflect the diverse landscape of research activities within the health domain.

While expanding the scope to "health-related research," the SLMC-IERC acknowledged certain limitations. For instance, the challenge of establishing clear distinctions between the ethics of social science research, behavioral studies, public health surveillance, and other research activities is recognized. Consequently, the current scope of "health-related research" is tailored to classic health-related research activities involving humans, such as observational research, clinical trials, biobanking, and epidemiological studies. This adjustment ensures a more comprehensive framework that accommodates a broader range of research endeavors within the realm of human health.

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Overall, this new SOP shall guide the ethics research committee in managing the ethical review of research protocols. It is with firm confidence that the reformulated SOP shall uphold and sustain the quality and ethicality of research conducted within and through SLMC, SLMCCM-WHQM and SLEC.

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION/ MAIN CHANGE	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	/			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with recommendations of FERCAP/PHREB surveyors Changes: 1. Added Policy Statement 2. Added Research Structure of SLMC 3. Updated description of SLMC-IERC SOP Manual 2025 edition	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	April 2025

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SOP Title: STRUCTURE AND COMPOSITION OF THE SLMC-IERM	SLMC-IERC SOP No.: SOP No. 1

1. STRUCTURE AND COMPOSITION OF THE SLMC-IERC

The St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC) is dedicated to safeguarding the rights and welfare of research participants, guided by core values of respect, integrity, and ethical responsibility. This Standard Operating Procedure (SOP) establishes the SLMC-IERC's structure and lays out the framework for its ethical oversight functions. It details the roles and responsibilities of our members and prescribes a fair, rigorous process for the review and approval of research protocols. By adhering to these procedures, the SLMC-IERC ensures that the conduct of all research under its purview is in alignment with the highest ethical standards.

SOP No. 1 outlines the following specific SOPs:

- SOP 1.1 Organizational Structure, Composition, Duties, and Responsibilities of the St. Luke's Medical Center Institutional Ethics Review Committee
- SOP 1.2 Confidentiality Agreements and Conflict of Interest Disclosure
- SOP 1.3 Training of SLMC-IERC Members and Secretariat
- SOP 1.4 Invitation and Responsibilities of Subject Matter Experts or External/ Independent Consultants
- SOP 1.5 Honoraria of SLMC-IERC Members, Secretariat and Subject Matter Expert or External/Independent Consultants
- SOP 1.6 Duties and Responsibilities of the SLMC-IERC Secretariat

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SOP Title: Organizational Structure, Composition, Duties and Responsibilities of the St. Luke's Medical Center Institutional Ethics Review Committee	SLMC-IERC SOP No.: SOP No. 1.1

1.1.1. PURPOSE

This SOP describes the organizational structure of the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC). It is aimed at ensuring that the standard process of selecting and replacing its Members, the criteria for membership, the duties and the responsibilities of the Chair, Vice Chair, Member-Secretary and Members (Regular and Alternate), and Independent Consultants are met.

1.1.2. SCOPE

This SOP outlines the organizational structure, composition, selection, and responsibilities of the SLMC-IERC.

1.1.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Establishment of the SLMC-IERC		
1. Appoint SLMC-IERC Chair and Members	SLMC President & CEO, R&B Head	At least 2 months before end of term
2. Establish the SLMC-IERC structure and reporting framework	SLMC President & CEO, R&B Head, SLMC-IERC Chair	Upon establishment
3. Ensure the SLMC-IERC operates independently while maintaining its reporting line to the SLMC President & CEO	SLMC-IERC	Continually with periodic reviews
4. Dissolve SLMC-IERC following due process, if necessary	SLMC President & CEO	As needed
Step 2. Formation of the SLMC-IERC Executive Committee		
1. Set the composition and leadership roles of the Executive Committee	R&B Head, SLMC-IERC Chair	Every 2 years or as needed
2. Establish the core functions of the SLMC-IERC Executive Committee	SLMC-IERC Executive Committee	Every 2 years or as needed

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Recommend and appoint candidates for SLMC-IERC Executive Committee Officers	SLMC President & CEO, R&B Head, SLMC-IERC Chair	At least 2 months before end of term
4. Establish the responsibilities of the SLMC-IERC Executive Committee a) Chair b) Vice-Chair c) Member-Secretary	SLMC-IERC Executive Committee	Every 2 years or as needed
5. Establish criteria for SLMC-IERC Officer Vacancies	SLMC-IERC Chair	Every 2 years or as needed
a) Assume the role as Chair until a new SLMC-IERC Chair is appointed	SLMC-IERC Vice-Chair	When SLMC-IERC Chair's position is vacated
b) Fill other vacancies	SLMC President & CEO, R&B Head, SLMC-IERC Chair	As needed
Step 3. Formation of the SLMC-IERC Membership		
1. Define the Terms of Reference for membership	SLMC-IERC Chair	Every 2 years or as needed
2. Designate and clarify the role of Alternate Members	SLMC-IERC Chair	Every 2 years or as needed
3. Appoint Regular and Alternate Members	SLMC President & CEO, R&B Head, SLMC-IERC Chair	Every 2 years or as needed
4. Invite Subject Matter Experts/External Consultants when specialized input is needed	SLMC-IERC Chair	As needed per protocol review

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 4. Establishment of roles and responsibilities of the SLMC-IERC		
1. Define the roles and responsibilities of the SLMC-IERC in evaluating research involving human participants	SLMC-IERC Chair, Members	Every 2 years or as needed
2. Establish the requirements for SLMC-IERC meeting and quorum	SLMC-IERC Chair, Members	Every 2 years or as needed
3. Develop the SOP for issuance of Ethical Clearance	SLMC-IERC Chair, Members	Every 2 years or as needed
4. Define the responsibilities of the SLMC-IERC for ongoing reviews and authority	SLMC-IERC Chair, Members	Every 2 years or as needed
Step 5. Establishment of the responsibilities of SLMC-IERC Members		
1. Clarify general responsibilities of the SLMC-IERC Regular and Alternate Members	SLMC-IERC Chair, Members	Every 2 years or as needed
2. Define the responsibilities of the SLMC-IERC Lay Member	SLMC-IERC Chair	Every 2 years or as needed
3. Define ad hoc responsibilities of the SLMC-IERC Members • Member-in-Charge of Screening Review and Risk Assessment • Member-in-Charge of Amendments • Member-in-Charge of Serious Adverse Events (SAE) • Member-in-Charge of Responses to Notice of Action (NOA) • Member-in-Charge of Protocol Deviations and Protocol Violations • Member-in-Charge of Continuing Review/Progress Reports	SLMC-IERC Chair	Every 2 years or as needed

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 6. Establishment of SOP for resignation, disqualification, withdrawal of appointment, and replacement of SLMC-IERC Members		
1. Submit written letter addressed to the SLMC President & CEO through the SLMC-IERC Chair, a copy furnished to the R&B Head	SLMC-IERC Members	Upon resignation
2. Disqualify or withdraw appointments based on meeting attendance, conflicts of interest, and confidentiality violations.	SLMC-IERC Chair	As needed
3. Replace resigned members based on recommendations from the SLMC-IERC Chair and R&B Head.	SLMC President & CEO, SLMC-IERC Chair, R&B Head	As needed

1.1.4. PROCEDURES

Step 1. Establishment of the SLMC-IERC

1. The SLMC President & CEO, upon the recommendation by the Research and Biotechnology Group (R&B) Head, shall appoint the SLMC-IERC Chair and members every two (2) years to ensure effective oversight of research ethics activities, in accordance with the SLMC organizational structure below:

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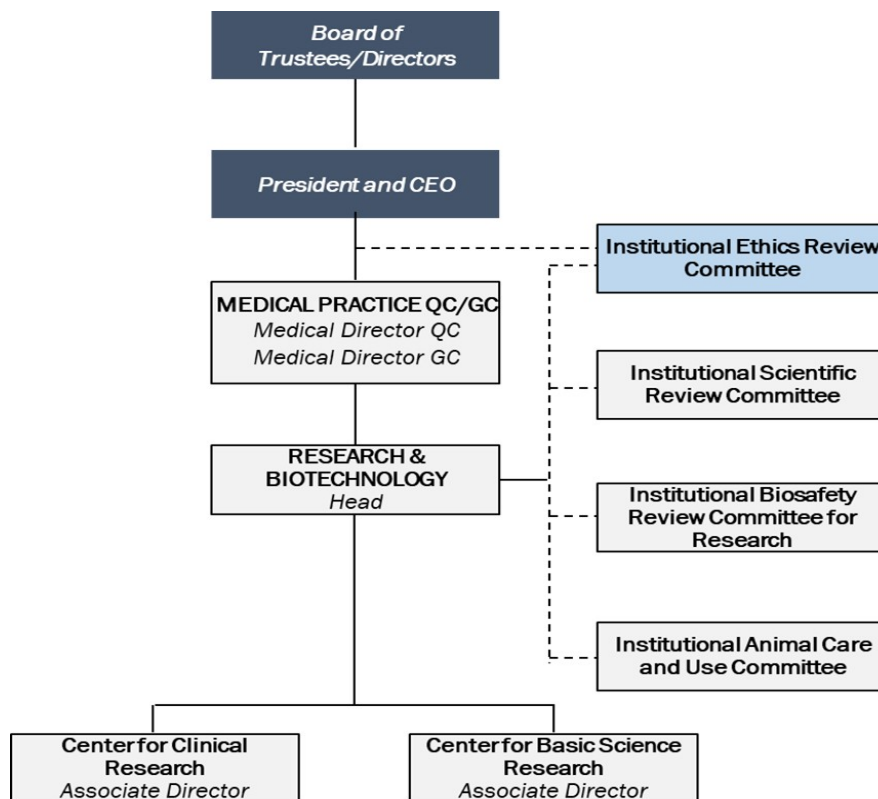


Figure 2: SLMC Table of Organization

2. The SLMC-IERC shall function under the following reporting and implementation framework:
 - SLMC President & CEO as the appointing authority
 - R&B Head as the endorsing officer
 - SLMC-IERC Chair as the recommending officer
 - R&B Office of Research Integrity (ORI) as the implementing office (*See related policy on Functional Group Policy of Research and Biotechnology Group*)
3. The SLMC-IERC shall operate independently to uphold impartiality, protection from external pressure and undue influence, while maintaining its reporting line to the SLMC President & CEO.
4. The SLMC President & CEO reserves the authority to dissolve the SLMC-IERC, if warranted, after due process.

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Step 2. Formation of the SLMC-IERC Executive Committee

1. Composition

The SLMC-IERC Executive Committee, composed of the Chair, Vice-Chair, and Member-Secretary. This Committee shall provide strategic leadership and operational oversight in accordance with this SOP.

2. Functions

The core functions of the SLMC-IERC Executive Committee shall include, but are not limited to, the following:

- i. Addressing review issues and administrative concerns;
- ii. Designating and coordinating with SLMC-IERC Members specifically charged with *ad hoc* functions, such as timely and expert evaluation of initial submissions; amendments; responses to notices of action (NOA); protocol deviations and violations, serious adverse events (SAE); continuing review and progress reports;
- iii. Assessing internal audit results and recommending actions;
- iv. Discussing member participation in continued ethics training;
- v. Resolving complaints, queries, and reports on ethical research misconduct;
- vi. Deliberating on the proposed SOP drafts;
- vii. Supporting training initiatives for SLMC-IERC Committee Members and Secretariat to enhance administrative efficiency.

3. Selection and Designation of the SLMC-IERC Officers

- a) The R&B Head shall recommend candidates for Chair, Vice-Chair, and Member-Secretary from among the Regular Members (see Step 3.3) at least two months before the end of their term in March.
- b) The SLMC President & CEO shall appoint the recommended officers.
- c) The tenure for the Executive Committee shall be set at two years, subject to reappointment
- d) The term shall commence on April 1 and conclude on March 31 two years later.

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4. Responsibilities of the SLMC-IERC Executive Committee

a) SLMC-IERC Chair

- i. Overseeing a preliminary review of all research protocols to determine the type of review. The SLMC-IERC Chair can enlist Regular Members as *ad hoc* members-in-charge for initial evaluation of submissions;
- ii. Creating the agenda and presiding over SLMC-IERC meetings;
- iii. Assigning SLMC-IERC Members to serve as Primary Reviewers;
- iv. Ensuring that final decisions are reached on all reviewed research protocols;
- v. Ensuring that the SLMC-IERC responds appropriately to issues including but not limited to participant complaints, non-compliance findings, loss of records or study drugs, adverse events, significant protocol changes, etc.;
- vi. Signing official communications such as Meeting Notices, Notices of Action to Principal Investigators/Project Leaders;
- vii. Authorizing Ethical Clearance on behalf of the SLMC-IERC;
- viii. Communicating the SLMC-IERC's decisions to Principal Investigators/Project Leaders;
- ix. Representing SLMC at ethics symposiums or meetings, subject to clearance from the R&B Head;
- x. Submitting annual report to the Philippine Health Research Ethics Board (PHREB).

b) SLMC-IERC Vice-Chair

- i. Acting as SLMC-IERC Chair in the Chair's absence;
- ii. Undertaking additional tasks as delegated by the SLMC-IERC Chair.

c) Responsibilities of the SLMC-IERC Member-Secretary

- i. Documenting meeting proceedings and preparing minutes in real-time;
- ii. Undertaking additional tasks as delegated by the SLMC-IERC Chair.

5. SLMC-IERC Officer Vacancies

- a) If the SLMC-IERC Chair's position is vacated, the Vice-Chair shall assume the role until a new Chair is appointed.
- b) Other vacancies shall be filled based upon recommendations of the SLMC-IERC Chair, endorsement of the R&B Head, and approval of the SLMC President & CEO.

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Step 3. Formation of the SLMC-IERC Membership

1. Terms of Reference for Membership

- a) The SLMC-IERC shall comprise of a minimum of nine (9) Regular Members, including:
 - o Scientific and/or medical members (e.g. licensed physicians);
 - o Non-scientific members, with at least one (1) non-affiliated and one (1) lay person.
- b) The SLMC-IERC Members shall be selected based on qualifications, relevant expertise, interest in ethical and/or scientific research, and commitment to actively participate in SLMC-IERC activities.
- c) The SLMC-IERC shall maintain diversity in its membership, ensuring adequate representation across different backgrounds, age groups, and genders.

2. Designation and Role of Alternate Members

- a) In anticipation of circumstances when Regular Members are unavailable and could affect quorum, SLMC-IERC Chair shall recommend a set of Alternate Members to serve in the SLMC-IERC.
- b) The Alternate Members shall hold same responsibilities and voting privileges as Regular Members.

3. Appointment of Members

- a) The Regular and Alternate Members of the SLMC-IERC shall be appointed by the SLMC President & CEO, upon endorsement of the R&B Head, and recommendation of the SLMC-IERC Chair. (*Refer to SLMC-IERC Template # 01A Letter of Appointment, Template # 01B Roles and Responsibilities of the SLMC-IERC Members, Template # 01C SLMC-IERC Composition*).
- b) The Regular and Alternate Members of the SLMC-IERC shall be appointed for a term of two (2) years. There shall be no limit to the number of terms a Member is reappointed.
- c) Recommendations for reappointment shall be submitted to the SLMC President & CEO at least two months before the end of their term in March.
- d) The term shall begin on April 1st of the year following appointment and conclude on March 31st of the second year.
- e) Upon appointment, each SLMC-IERC Member shall sign a Disclosure of Conflict of Interest Form (e.g. financial interests in a pharmaceutical company, etc.) (*Refer to*

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SLMC-IERC Form # 01B) and a Confidentiality Agreement regarding meeting deliberations, applications, information on research participants, and other confidential matters.

4. Subject Matter Experts or External/Independent Consultants

- a) If the SLMC-IERC lacks the necessary expertise to evaluate a particular study, the SLMC-IERC Chair may invite Subject Matter Experts or External/Independent Consultants to serve as Primary Reviewers. Their input shall be recorded and considered during deliberations.
- b) The Subject Matter Experts or External/Independent Consultants shall not have voting privileges.

Step 4. Establishment of Roles and Responsibilities of the SLMC-IERC

1. Ethical Evaluation of Research Involving Human Participants

- a) The SLMC-IERC is responsible for determining if activities within a protocol qualify as research involving human participants.
- b) Serving as a central review body, the SLMC-IERC reviews onsite clinical studies and research involving human subjects, including those concerning identifiable human materials or data.
- c) The SLMC-IERC shall review essential documents of clinical research studies (i.e. all phases of clinical trials including investigator-initiated, observational, databank/registry and post marketing surveillance studies) submitted to SLMC-IERC to safeguard the rights, dignity and welfare of human participants.
- d) The SLMC-IERC shall identify and recommend an External/Independent Consultant, a known expert, to provide additional information about a study when necessary.
- e) The SLMC-IERC shall ensure that clinical research studies shall be conducted in accordance with Philippine laws and National Ethical Guidelines for Research Involving Human Participants (2022) by Philippine Health Research Ethics Board (PHREB), Declaration of Helsinki (2024 ed.), and International Conference on Harmonization (ICH) for Good Clinical Practice (GCP) E6(R2) (2016).
- f) The SLMC-IERC shall recommend the approval of sponsor-initiated clinical trials and investigator-initiated research studies involving human participants based on any or all of the following conditions:
 - o all ethical issues have been addressed;

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- the protocol is compliant with Good Clinical Practice guidelines;
- the protocol has been revised in accordance with the Notice of Action issued by the SLMC-IERC Secretariat to the Principal Investigator/Project Leader and the SLMC-IERC has made a continuing review of the response. *(Please refer to SLMC-IERC SOP # 3.6 Review of Protocols that Require Revisions after Initial Review)*

2. Meeting and Quorum Requirement

- a) Regular meetings of the SLMC-IERC are essential to facilitate timely and collaborative review of research protocols and ensure ongoing oversight of ethical compliance in research practices.
- b) A quorum for any SLMC-IERC meeting shall consist of more than half of the members (50% plus one), and must not be fewer than five members in attendance. This quorum must include at least one lay member, one non-affiliated member, and representation from both female and male members to ensure diverse perspectives and equity in the review process.
- c) The SLMC-IERC shall convene for meetings on the following occasions:
 - Regular meetings held every 3rd Wednesday of the month or on a date unanimously agreed upon by the SLMC-IERC Members.
 - Emergency meetings convened by the SLMC-IERC Chair
 - *Ad hoc* assignments designated by the Philippine Food and Drug Administration (PFDA), Philippine Health Ethics Review Board (PHREB), and SLMC President & CEO or its representative.

3. Issuance of Ethical Clearance

- a) The SLMC-IERC shall issue the Ethical Clearance (EC) to indicate approval following review of the Protocol. *(Refer to SLMC-IERC Form # 03A)*
- b) The Ethical Clearance shall indicate the dates of review, approval, validity and responsibilities of the Principal Investigator/Project Leader.
- c) The Ethical Clearance shall be valid for a maximum of one (1) year. Validity may be shorter depending on the level of risk *(Refer to SLMC-IERC SOP # 4.1, Step 1.2)*.
- d) Extension of the validity of the Ethical Clearance shall be granted upon compliance with the following requirements:
 - written request of the Principal Investigator/Project Leader;
 - submission of progress report (using *SLMC-IERC Form # 04A*);
 - favorable evaluation of the progress report; and

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- payment of extension fee.

4. Ongoing Reviews and Authority

- a) The SLMC-IERC shall evaluate reports on adverse drug reactions (ADRs) / serious adverse events (SAEs) / suspected unexpected serious adverse reactions (SUSARs) and perform continuing review of each ongoing trial at intervals appropriate of the risk to human subjects or at least once a year (*based on the SLMC-IERC review approval date*) using the SLMC-IERC Continuing Review/Progress Report Form (*SLMC-IERC Form # 04A*) issued by the SLMC-IERC Secretariat (*Refer to policy on Monitoring of Clinical Safety of Investigational Drugs and SLMC-IERC SOP # 4.2*).
- b) Upon the recommendation of the SLMC-IERC Chair and appointment by the SLMC President & CEO, Regular Members may be charged with reviewing serious adverse events (SAEs). These members are responsible for ensuring that SAEs receive a prompt and expert evaluation, consistent with the participant safety and research integrity duties.
- c) The SLMC-IERC shall have authority to suspend or terminate approval of human research not being conducted in accordance with the SLMC-IERC's requirements or that has been associated with unexpected serious harm to subjects.
- d) The SLMC-IERC may observe or authorize the CHRP to observe, in certain occasions (*e.g. numerous reports of protocol deviations / violations, onsite SAEs & SUSARs and complaints*) the consent process and the conduct of the human research.
- e) The SLMC-IERC shall evaluate conflict of interest (COI) of investigators and research staff and have the final authority to decide whether the COI and management plan, if any, allow the human research to be approved.

Step 5. Responsibilities of SLMC-IERC Members

1. General Responsibilities

Every Regular and Alternate Member of the SLMC-IERC shall have the following responsibilities:

- a) Reviewing the minutes from previous meetings as provided via email in advance of upcoming full board meetings;
- b) Safeguarding the confidentiality of all documents and discussions pertaining to SLMC-IERC deliberations and decisions;

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- c) Declaring any potential conflicts of interest with research protocols under review to maintain objectivity;
- d) Participating consistently in SLMC-IERC meetings and engage in the review and evaluation of clinical research protocols, responding to both full and expedited review requests;
- e) Engaging in ongoing evaluation processes for approved research protocols, contributing to their continuous oversight;
- f) Reviewing and providing insights on progress reports, protocol amendments, adverse event reports, and instances of protocol deviation or violation;
- g) Acquiring a thorough understanding of the SLMC-IERC SOP and adhere to these guidelines;
- h) Participating in workshops, seminars, and conferences related to research ethics to enhance expertise and stay informed about current practices;
- i) Maintaining an up-to-date Good Clinical Practice (GCP) certification, with a validity period of at least three year;
- j) Providing an updated Curriculum Vitae at the initiation of each term of appointment.

2. Responsibilities of the Lay Member

The SLMC-IERC Lay Member shall have the following responsibilities:

- a) Reviewing informed consent to ensure meaningful participant protection in research;
- b) Evaluating the risks and benefits of research participants
- c) Reviewing informed consent to ensure that language and other aspects of the study are comprehensible by a Lay Member
- d) Ensuring his/her presence always in SLMC-IERC meetings to meet the quorum requirement *(50% plus one, but not less than five (5), including a lay member, a non-affiliated member and presence of both female and male members).*

3. Ad Hoc Responsibilities

- a) Regular Members may also be charged with ad hoc responsibilities to ensure a responsive and efficient review process. These responsibilities may include, but are not limited to:
 - i. Evaluating initial submissions to determine whether they meet the required ethical and scientific standards;
 - ii. Assessing amendments to ongoing studies to ensure continued compliance with ethical guidelines;

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- iii. Reviewing responses to Notices of Action (NOA) to verify that required modifications have been appropriately addressed;
 - iv. Investigating protocol deviations and violations to assess their impact and recommend corrective actions;
 - v. Evaluating reports of Serious Adverse Events (SAE) to protect participant safety and the integrity of the research;
 - vi. Conducting continuing reviews and analyzing progress reports to oversee the ongoing conduct of approved research studies.
 - vii. Reviewing both initial and post-approval submissions of research protocols when assigned as a primary reviewer.
- b) The primary role of Regular Members in-charge of *ad hoc* responsibilities is to safeguard the rights and well-being of the human participants in research.
- c) The **Member-in-Charge of Screening Review and Risk Assessment** is responsible for the following:
 - i. Conducting initial screening to verify that protocol submissions are complete and adherent to SLMC-IERC submission guidelines;
 - ii. Examining research protocols to gain a clear understanding of the research objectives and study approach;
 - iii. Evaluating the level of risk and complexity to decide the intensity and type of review that the protocol requires;
 - iv. Identifying and recommending type of reviewer expertise that corresponds to the research focus;
 - v. Communicating any recommendations or concerns to the SLMC-IERC for further deliberation and action.
 - vi. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws, standards of professional conduct and practice, and community mores, values, and needs;
 - vii. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study
- d) The **Member-in-Charge of Amendments** is responsible for the following:
 - i. Evaluating all protocol and informed consent form amendments submitted by the Principal Investigator;

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- ii. Reporting during full-board meeting the findings and recommendation of the protocol amendment reports;
 - iii. Notifying the SLMC-IERC Chair immediately whether, in their opinion, the risk outweighs potential benefit, other participants may be at risk, or risks have not been appropriately minimized;
 - iv. Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines;
 - v. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws, standards of professional conduct and practice, and community mores, values, and needs;
 - vi. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study.
- e) The **Member-in-Charge of Serious Adverse Events (SAE)** is responsible for the following:
- i. Evaluating all Serious Adverse Events (SAE) reported by the Principal Investigator;
 - ii. Reporting during full-board meetings the findings and recommendation of the Serious Adverse Events (SAE) reports;
 - iii. Notifying the SLMC-IERC Chair immediately whether, in their opinion, the risk outweighs potential benefit, other participants may be at risk, or risks have not been appropriately minimized;
 - iv. Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines;
 - v. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws, standards of professional conduct and practice, and community mores, values, and needs;
 - vi. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study.
- f) The **Member-in-Charge of Responses to Notice of Action (NOA)** is responsible for the following:
- i. Evaluating all submitted Responses to Notice of Action (NOA) by the Principal Investigator;

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- ii. Reporting during full-board meetings the findings and recommendation of the Response to Notice of Action (NOA) submitted;
 - iii. Notifying the SLMC-IERC Chair immediately whether, in their opinion, the risk outweighs potential benefit, other participants may be at risk, or risks have not been appropriately minimized;
 - iv. Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines;
 - v. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws,
 - vi. standards of professional conduct and practice, and community mores, values, and needs;
 - vii. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study.
- g) The **Member-in-Charge of Protocol Deviations and Protocol Violations** is responsible for the following:
- i. Evaluating all protocol deviations and protocol violations reported by the Principal Investigator;
 - ii. Reporting during full-board meeting the findings and recommendation of the protocol deviations and protocol violations reports;
 - iii. Notifying the SLMC-IERC Chair immediately whether, in their opinion, the risk outweighs potential benefit, other participants may be at risk, or risks have not been appropriately minimized;
 - iv. Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines;
 - v. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws, standards of professional conduct and practice, and community mores, values, and needs;
 - vi. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study.

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- h) The **Member-in-Charge of Continuing Review/Progress Reports** is responsible for the following:
- Evaluating all continuing review/progress reports submitted by the Principal Investigator;
 - Reporting during full-board meetings the findings from and recommendations for the continuing review/progress reports;
 - Notifying the SLMC-IERC Chair immediately whether, in their opinion, the risk outweighs potential benefit, other participants may be at risk, or risks have not been appropriately minimized;
 - Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines;
 - Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws,
 - standards of professional conduct and practice, and community mores, values, and needs;
 - Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study.

Step 6. Resignation, Disqualification, Withdrawal of Appointment and Replacement of SLMC-IERC Members

- An SLMC-IERC Member may resign from the SLMC-IERC at any time during his/her term by submitting a written letter addressed to the SLMC President & CEO through the SLMC-IERC Chair. A copy of the letter shall be furnished to the R&B Head.
- An SLMC-IERC Member may be recommended by the SLMC-IERC Chair for disqualification and/or withdrawal of Appointment for any of the following reasons:
 - Failure without justifiable reason to attend three (3) consecutive meetings of the SLMC-IERC without any valid reason or six (6) absences within a 12-month period;
 - Failure to disclose Conflict of Interest as herein defined. (COI refers to circumstances where a primary interest, such as patient health, is compromised by a secondary interest such as financial profit);
 - Violation of the Confidentiality Rule;
 - Other justifiable causes as determined by the SLMC-IERC.

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP Title: Organizational Structure, Composition, Duties and Responsibilities of the St. Luke's Medical Center Institutional Ethics Review Committee	SLMC-IERC SOP No.: SOP No. 1.1

3. Replacement of the resigned SLMC-IERC Member shall be made by the President and CEO, upon recommendation of the SLMC-IERC Chair and R&B Head.

1.1.5. REFERENCES

Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

Republic of the Philippines (2013). Republic Act No. 10532 - Philippine National Health Research System Act of 2013. Manila: Republic of the Philippines.

Republic of the Philippines. (2012). Republic Act No. 10173 - Data Privacy Act of 2012. Manila: Republic of the Philippines.

World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.

World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

World Medical Association. (2024). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

—Nothing Follows—

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Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION/ MAIN CHANGE	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors; Improvement of processes 1. Addition of President and CEO in the Organizational Structure 2. Updated Table of Organization 3. IERC membership 4. Removal of Head of CHRP as Ex-Officio of SLMC-IERC 5. Addition of the following: a. Responsibilities of the SLMC-IERC Executive Committee b. Responsibilities of Members-in-charge of the following: Screening Review and Risk Assessment, Amendments, SAE reports, Response to Notice of Action, Protocol deviation and protocol violation reports, Continuing Review/ Progress Reports 6. Updated References 7. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U, Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☒ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Confidentiality Agreements and Disclosure of Conflict of Interest	SLMC-IERC SOP No.: SOP No. 1.2

1.2.1. PURPOSE

The purpose of this SOP is to ensure that the Members of the SLMC-IERC read, understand, accept, sign and date an Agreement on Confidentiality and Conflict of Interest form upon appointment. This process ensures that the SLMC-IERC Members disclose conflict of interest and maintain confidentiality on the documents and issues taken up during SLMC-IERC meetings.

1.2.2. SCOPE

This SOP covers the signing of Agreement on Confidentiality and Conflict of Interest forms by the SLMC-IERC Members and the filing of the signed forms by the SLMC-IERC Secretariat.

1.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Distribute COI Confidentiality and Conflict of Interest Forms to SLMC-IERC Members (new and reappointed)	SLMC-IERC Initial Submissions Coordinator	Within two weeks
Step 2. Sign, date and return the form	SLMC-IERC Members (new and reappointed)	Within two weeks
Step 3. Provide a copy of signed form to the SLMC-IERC Member	SLMC-IERC Initial Submissions Coordinator	Within two weeks
Step 4. File the signed Forms in the Master Files of SLMC-IERC Members	SLMC-IERC Initial Submissions Coordinator	Within two weeks

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☒ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Confidentiality Agreements and Disclosure of Conflict of Interest	SLMC-IERC SOP No.: SOP No. 1.2

1.2.4. PROCEDURES

- Step 1. The SLMC-IERC Initial Submissions Coordinator shall provide newly appointed and reappointed SLMC-IERC Members with the Agreement on Confidentiality and Conflict of Interest Form (*SLMC-IERC Form # 01A*) within two (2) weeks from their appointment or reappointment.
- Step 2. The SLMC-IERC Members shall sign, date and return the Agreement within two (2) weeks of receipt.
- Step 3. The SLMC-IERC Initial Submissions Coordinator shall provide each SLMC-IERC Member a copy of their signed form within two (2) weeks of execution.
- Step 4. The SLMC-IERC Initial Submissions Coordinator shall file the signed forms in the “Master Files of SLMC-IERC Members” within two (2) weeks of execution.

1.2.5. REFERENCES

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.
- Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothings Follows—

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☒ Regulatory		Revision Effective Date: April 1, 2025
SOP Title: Confidentiality Agreements and Disclosure of Conflict of Interest		SLMC-IERC SOP No.: SOP No. 1.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors 1. Replaced Secretariat with Initial Submissions Coordinator 2. Updated list of References 3. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☒ Regulatory	Revision Effective Date: April 1, 2025
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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP Title: Training of SLMC-IERC Members and Secretariat	SLMC-IERC SOP No.: SOP No. 1.3

1.3.1. PURPOSE

The purpose of this SOP is to ensure that Members of the SLMC-IERC and SLMC-IERC Secretariat team regularly attend seminars, training, workshops, or conferences in order to maintain and enhance their competence and skills through an updated knowledge of research ethics and guidelines. Moreover, ICH-GCP requires regular training and updates of all SLMC-IERC Secretariat involved in human research every year. This SOP will also ensure that the SLMC-IERC Members maintain the validity of their GCP certification.

1.3.2. SCOPE

This SOP outlines the procedures from identification of seminars, training, workshops, or conferences to sharing learnings with the full board.

1.3.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Identify seminars, trainings, workshops and conferences	SLMC-IERC Members and Secretariat, Head of Office of Research Integrity (ORI)	Annual and as needed
Step 2. Identify participants (SLMC-IERC Members/Secretariat) for specific events	SLMC-IERC Chair Head of ORI	Within 2 weeks of event identification
Step 3. Prepare letter requesting for the approval and budget for the activity	Head of ORI	Within 1 week of participant selection
Step 4. Approve attendance and funding	President and CEO or Head of R&B	Within 2 weeks of submission of request
Step 5. Attend seminar, training, workshop or conference	SLMC-IERC Members and Secretariat	As scheduled by host organization

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 6. File Training Certificates in digital 201 Files	SLMC-IERC Secretariat	Within 1 week after event
Step 7. Conduct echo seminar to SLMC-IERC full board meeting	Attendee/s from SLMC-IERC Members or Secretariat	During next scheduled full board meeting or as scheduled

1.3.4. PROCEDURES

- Step 1. The SLMC-IERC Members, Secretariat, and Head of R&B Office of Research Integrity (ORI) shall regularly identify and monitor available training courses, workshops, and conferences on research ethics such as advanced training on ethical issues and concerns, ethics review committees, and other related topics at least annually or as opportunities arise.
- Step 2. The SLMC-IERC Secretariat shall ensure that each SLMC-IERC Member and Secretariat undergoes:
- Good Clinical Practice (GCP) training every three (3) years
 - Research ethics or related training at least once annually
- Step 3. The SLMC-IERC Chair and Head of R&B ORI shall select appropriate SLMC-IERC Members and Secretariat staff to attend identified events within two (2) weeks of confirming the event.
- Step 4. The Head of R&B ORI shall prepare a formal letter requesting approval for attendance and budget and submit it to the Head of Research & Biotechnology (R&B) within one (1) week of participant identification.
- Step 5. The Head of R&B or SLMC President & CEO shall approve the request in accordance with institutional policy within two (2) weeks of submission.

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Step 6. After attending the training, participants shall submit their certificate or proof of attendance to the SLMC-IERC Secretariat, who shall file the certificate in the digital 201 File under “Master Files of SLMC-IERC Members” within one (1) week of receipt.

Step 7. The attendee shall conduct an echo seminar to share learnings during the next scheduled full board meeting or as scheduled. This will count as part of the SLMC-IERC’s continuing training efforts.

1.3.5. REFERENCES

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.
- World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

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SOP Title: Training of SLMC-IERC Members and Secretariat		SLMC-IERC SOP No.: SOP No. 1.3

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Simplified scope 2. Head of R&B or SLMC President and CEO shall approve request for trainings, etc. in accordance with the SLMC Policy Approving Authority for Executives. 3. Updated List of References 4. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Invitation and Responsibilities of Subject Matter Experts or External/Independent Consultants	SLMC-IERC SOP No.: SOP No. 1.4

1.4.1. PURPOSE

The purpose of this SOP is to describe the process of obtaining the services of an expert to serve as Subject Matter Expert or External/Independent Consultant on matters outside the expertise of members of the SLMC-IERC, and to guide the Subject Matter Expert or External/Independent Consultant in his/her responsibilities in the review of a clinical research protocol.

1.4.2. SCOPE

This SOP covers the process of determining the need, identification and appointment of Subject Matter Expert or External/Independent Consultants as well as their responsibilities when reviewing of research protocols.

1.4.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Selection of Subject Matter Expert or External/Independent Consultant		
1. Invite a Subject Matter Expert or External/Independent Consultant to be part of the SLMC-IERC roster.	SLMC-IERC Chair	As needed
2. Sign of Agreement of Confidentiality and Disclosure of Conflict of Interest Form	Subject Matter Expert or External/Independent Consultant	Upon appointment
3. File the signed Agreement of Confidentiality and Disclosure of Conflict of Interest form	SLMC-IERC Initial Submissions Coordinator	Within 2 weeks

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Invitation and Responsibilities of Subject Matter Experts or External/Independent Consultants	SLMC-IERC SOP No.: SOP No. 1.4

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 2. Responsibilities of the External/Independent Consultant		
1. Participate in the review of a specific protocol and provide inputs on specific issues related to one's expertise - o Sign the Agreement of Confidentiality and Disclosure of Conflict of Interest form if newly invited expert - o Diligently reads the clinical research protocol details - o Conducts literature searches - o Fill up the Ethics Review Form for External/Independent Consultants with necessary and relevant comments regarding the protocol - o Attend the SLMC-IERC full board meeting and actively participate in the discussion of the clinical research.	Subject Matter Expert or External/Independent Consultant	Within 2 weeks
2. Abstain from voting on the protocol	SLMC-IERC Initial Submissions Coordinator	During the full board review process

1.4.4. PROCEDURES

Step 1. Selection of the Subject Matter Expert or External/Independent Consultant

1. The SLMC-IERC Executive Chair may invite various professionals with specific scientific expertise to be part of the SLMC-IERC roster of Subject Matter Experts or External/Independent Consultants representing expertise not present in the current panels.
2. The Subject Matter Expert or External/Independent Consultant shall sign an Agreement of Confidentiality and Disclosure of Conflict of Interest form upon his/her appointment (SLMC-IERC Form # 01B).

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SOP Title: Invitation and Responsibilities of Subject Matter Experts or External/Independent Consultants	SLMC-IERC SOP No.: SOP No. 1.4

3. The SLMC-IERC Initial Submissions Coordinator shall file the signed Agreement of Confidentiality and Disclosure of Conflict of Interest form in the “Master files of Subject Matter Expert or External/Independent Consultants.”

Step 2. Responsibilities of the Subject Matter Expert or External/Independent Consultant

1. The Subject Matter Expert or External/Independent Consultant shall participate in the review of a specific protocol and give his/her inputs on specific issues related to his expertise. He/she shall perform the following:
 - Sign the Agreement of Confidentiality and Disclosure of Conflict of Interest form (*SLMC-IERC Form # 01B*)
 - Diligently reads the clinical research protocol details
 - Conducts literature searches
 - Fills up the Ethics Review Form for Subject Matter Expert or External/Independent Consultants (*SLMC-IERC Form #02G*) with necessary and relevant comments regarding the protocol
 - Attend the SLMC-IERC full board meeting and actively participate in the discussion of the clinical research.
2. The Subject Matter Expert or External/Independent Consultant shall not have any voting rights during full board meetings.

1.4.5. REFERENCES

Association for the Accreditation of Human Research Protection Programs, Inc. (2018). Evaluation Instrument for Accreditation. Washington, DC: Association for the Accreditation of Human Research Protection Programs, Inc.

Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

---Nothing Follows---

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory		Revision Effective Date: April 1, 2025
SOP Title: Invitation and Responsibilities of Subject Matter Experts or External/ Independent Consultants		SLMC-IERC SOP No.: SOP No. 1.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Insertion of "Subject Matter Expert" 2. Renumbering of Template 01A to 01b 3. Renumbering of Form 06 to Form 02G 4. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Honoraria of SLMC-IERC Members, Secretariat and Subject Matter Expert or External/Independent Consultants	SLMC-IERC SOP No.: SOP No. 1.5

1.5.1 PURPOSE

The purpose of this SOP is to ensure that the SLMC-IERC Members, Secretariat and Subject Matter Expert or External/Independent Consultants are granted honoraria for their work in the committee.

1.5.2 SCOPE

This SOP covers the process of recommending, approving, and processing of the honoraria for the SLMC-IERC Members, Secretariat and Subject Matter Expert or External/Independent Consultants.

1.5.3 WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Recommend granting of honorarium for SLMC-IERC Members and Subject Matter Expert or External/Independent Consultants and possible workload-based increase	Head of R&B	Annually or as needed
Step 2. Request for honorarium payment	SLMC-IERC Secretariat Coordinators	Monthly
Step 3. Prepare honorarium request	CCT Coordinator	Monthly
1. Secure signed Auto Credit Bank Account Enrollment forms from members not yet enrolled in direct deposit.	CCT Coordinator	As needed
Step 4. Review and approve request	R&B ORI Head R&B Head	Within 3 working days of preparation
Step 5. Forward signed request and enrollment forms to SLMC Accounting Department.	CCT Coordinator	Within 3 working days of preparation

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Honoraria of SLMC-IERC Members, Secretariat and Subject Matter Expert or External/Independent Consultants	SLMC-IERC SOP No.: SOP No. 1.5

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 6. File soft copy of honorarium request.	CCT Coordinator	Within 1 working day after submission to Accounting
Step 7. Deposit honorarium directly to designated bank accounts.	SLMC Accounting Department	Within standard payroll cycle

1.5.4 PROCEDURES

Step 1. The Head of R&B shall recommend to the SLMC President & CEO the granting of honorarium to the SLMC-IERC Members and Subject Matter Expert or External/Independent Consultants for their work in the committee. The honorarium shall cover an amount for review of protocols, for attendance and participation in meetings and other SLMC-IERC activities and a year-end bonus. The Head of R&B may recommend an increase in the honorarium depending on the workload.

Step 2. The SLMC-IERC Secretariat Coordinators shall request from the R&B Center for Clinical Trials (CCT) Coordinator for the payment of honorarium to the SLMC-IERC Members and Subject Matter Expert or External/Independent Consultants on a monthly basis.

Step 3. The CCT Coordinator shall prepare the request for honorarium.

1. The CCT Coordinator shall obtain from each SLMC-IERC Member, Secretariat and External/Independent Consultant who is not yet enrolled for direct deposit, a signed Auto Credit Bank Account for Enrollment form, authorizing direct deposit of the honorarium to their designated bank account.

Step 4. The R&B Head shall approve and sign the request for honorarium verified by the R&B ORI Head.

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Step 5. The CCT Coordinator shall forward the signed request for honorarium and signed Auto Credit Bank Account for Enrollment forms, for those who are not yet enrolled, to the SLMC Accounting Department.

Step 6. The CCT Coordinator shall file soft copy of request in Check Prep IERC Honorarium folder.

Step 7. The SLMC Accounting Department shall deposit the honorarium directly to the designated bank accounts of the recipient.

1.5.5 REFERENCES

- Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.
- Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothing Follows—

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. CCT Administrator changed to CCT Coordinator 2. Instead of the Coordinator handling honorarium checks from Accounting and distributing them, payments will now be directly deposited into the recipients' bank accounts. 3. Update of References 4. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Duties and Responsibilities of the SLMC-IERC Secretariat	SLMC-IERC SOP No.: SOP No. 1.6

1.6.1. PURPOSE

The purpose of this SOP is to describe the duties and responsibilities of the SLMC-IERC Secretariat.

1.6.2. SCOPE

This SOP covers the duties and responsibilities of Secretariat in the providing administrative support to the SLMC-IERC.

1.6.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Designate SLMC-IERC Secretariat as the administrative support unit	Head of R&B Office of Research Integrity	Upon staffing or role change
Step 2. Provide overall direction and oversight for the SLMC Secretariat's operations.	SLMC-IERC Chair SLMC-IERC Manager	Continually
Step 3. Supervise daily Secretariat activities and ensure effective implementation of functions	SLMC-IERC Manager	Daily/Weekly
Step 4. Define responsibilities of the SLMC-IERC Secretariat 1. All SLMC-IERC Secretariat Staff 2. Submissions Processor 3. Initial Submission Coordinator 4. Amendments Coordinator 5. SAE and Noncompliance Coordinator 6. Progress Reports Coordinator	SLMC-IERC Chair SLMC-IERC Manager	Every 2 years or as needed

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1.6.4. PROCEDURES

Step 1. The Head of the R&B Office of Research Integrity (ORI) shall designate the SLMC-IERC Secretariat to serve as the administrative support unit of the SLMC-IERC, ensuring day-to-day coordination, documentation, and communication related to ethics review activities

Step 2. The SLMC-IERC Chair, in collaboration with the SLMC-IERC Manager, provides overall direction and oversight for the Secretariat's operations.

Step 3. The SLMC-IERC Manager is responsible for the day-to-day management and coordination of the Secretariat's activities to ensure the efficient and effective execution of all SLMC-IERC functions. Key responsibilities include:

- Overseeing the efficient execution of protocol reviews and committee meetings.
- Managing staff training and development.
- Ensuring the confidentiality of all SLMC-IERC documentation and communications.
- Collaborating with the SLMC-IERC Chair in providing overall direction for the Secretariat.

Step 4. The following are the responsibilities of the SLMC-IERC Secretariat:

1. All SLMC-IERC Secretariat Staff

- a) Maintaining confidentiality of all SLMC-IERC and communications;
- b) Responding to queries from Investigators on matters relevant to the functions/ activities/schedules, etc. of the SLMC-IERC;
- c) Assisting the SLMC-IERC Chair and the Manager in preparing the annual budget for the SLMC-IERC operations.
- d) Preparing reports and other matters to be presented at SLMC-IERC meetings;
- e) Performing other functions as assigned by the SLMC-IERC Executive Committee and Members;
- f) Adhering to the established SOPs and work collaboratively to ensure efficient and effective Secretariat operations.

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2. Submissions Processor

- a) Receiving, documenting, and recording all initial protocol submissions;
- b) Communicating with Principal Investigator (PI)/Project Leader regarding completeness of initial submissions;
- c) Assigning the EC Reference number for all complete initial submission of protocols and related documents;
- d) Forwarding the submitted protocol documents to SLMC-IERC Member-in-Charge of Screening Review and Risk Assessment for determination of type of review process and level of risk;
- e) Informing the SLMC-IERC Chair of the type of review and level of risk for the protocol documents;
- f) Logging of new protocol submission in the SLMC-IERC protocol database;
- g) Filing of protocol documents and accomplished Initial Review Forms in the digital protocol file folder;
- h) Receiving and categorizing all incoming emails (submissions, reports, inquiries, etc.), logging them in the email communication tracker, and taking one of the following actions:
 - o Responding to emails themselves for straightforward inquiries related to SLMC-IERC in general.
 - o Routing emails to the appropriate Coordinator for further processing (e.g., amendments to Amendments Coordinator, etc.).
- i) Performing initial data entry and maintenance of the SLMC-IERC electronic protocol database for newly submitted protocols.

3. Initial Submission Coordinator

- a) Forwarding the submitted protocol and related documents to the Chair for designation of SLMC-IERC Reviewers;
- b) Forwarding the complete protocols documents and Ethics Review Forms to the designated SLMC-IERC Primary Reviewers, Lay Members and/or Subject Matter Expert or External/Independent Consultant once it has been determined to undergo expedited review or full board review;
- c) Collating findings and recommendations of expedited reviews;
- d) Collating all essential documents for SLMC-IERC meetings and distributes these to SLMC-IERC Members at least two (2) weeks before the scheduled full board meeting;

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- e) Preparing the agenda and Minutes of Meetings of SLMC-IERC and sending to all SLMC-IERC Members at least two (2) days before a scheduled full board meeting via email;
- f) Preparing and distributing protocols, Ethics Review Forms, and communications to and coordinates with Subject Matter Expert or External/Independent Consultants the schedule of protocol presentation;
- g) Requesting the use and assuring the availability of the venue for SLMC-IERC meetings;
- h) Recording via Google Meet recorder and preparing Minutes of SLMC-IERC Meetings;
- i) Collecting and collating all accomplished Ethics Review Forms from the SLMC-IERC Reviewers;
- j) Preparing notification of outcome of review to the Principal Investigators/Project Leaders;
- k) Maintaining and updating the SLMC-IERC Protocol Database;
- l) Keeping and maintaining archives of the following: protocol files of each reviewed clinical research studies, agenda, notice and minutes of meetings, file of SLMC-IERC Members, attendance sheets, files of Subject Matter Expert or External/Independent Consultants, communications with Principal Investigators/Project Leaders, and other relevant documents
- m) Updating the electronic protocol database with information related to review assignments, meeting schedules, and review outcomes for initial submissions.

4. Amendments Coordinator

- a) Receiving and checking the completeness of amendment application documents;
- b) Communicating with PIs/Project Leaders if any missing information or clarifications are needed;
- c) Coordinating with SLMC-IERC Primary Reviewers and Member-in-charge of Amendments;
- d) Preparing the Protocol Amendments section of the agenda and Minutes of Meetings of SLMC-IERC;
- e) Preparing and forwarding notification to PIs/Project Leaders;

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- f) Updating SLMC-IERC electronic protocol database and Amendment database;
- g) Filing of all electronic and/or paper files of amendment documents to the digital protocol file folder.
- h) Updating the electronic protocol database and the Amendment database with information related to amendment submissions, reviews, and approvals.

5. SAE and Noncompliance Coordinator

- a) Receiving and check the completeness of reports on ADRs/SAEs/SUSARs and Protocol Violation/Deviation Reports;
- b) Communicate with PIs/Project Leaders if any missing information or clarifications are needed;
- c) Coordinate with SLMC-IERC Primary Reviewers, Pharmacologist (for ADR/SAE/SUSAR reports) and Member-in-charge of SAE Reports or Member-in-charge of Protocol Violation/Deviation;
- d) Preparing the sections of SAE Reports and Protocol Violation/Deviation Reports of the agenda and Minutes of Meetings of SLMC-IERC;
- e) Preparing and forwarding notification to PIs/Project Leaders;
- f) Updating the SLMC-IERC protocol database, databases for reports on ADRs/SAEs/SUSARs and Protocol Violation/Deviation Reports;
- g) Filing of all electronic and/or paper files of reports on ADRs/SAEs/SUSARs and Protocol Violation/Deviation Reports to the digital protocol file folder.
- h) Updating the electronic protocol database and the SAE/Noncompliance database with information related to reported events and investigations.

6. Progress Reports Coordinator

- a) Receiving and checking the completeness of Continuing Review/Progress/Final Reports documents;
- b) Communicating with PIs/Project Leaders if any missing information or clarifications are needed;
- c) Coordinating with SLMC-IERC Primary Reviewers and Member-in-charge of Continuing Review;
- d) Preparing the sections on Continuing Review/Progress Reports and Final Reports of the agenda and Minutes of Meetings of SLMC-IERC;

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- e) Preparing and forwarding notification to PIs/Project Leaders;
- f) Updating SLMC-IERC protocol database and Continuing Review/Progress/Final Reports database;
- g) Filing of all electronic and/or paper files of Continuing Review/Progress/Final Reports documents to the digital protocol file folder.
- h) Updating the electronic protocol database and the Progress Reports database with information related to continuing review, progress reports, and final reports.

1.6.5. REFERENCES

National Ethics Committee Standard Operating Procedures, version 2 (2015). Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

---Nothings Follows---

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	04-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Head of ORI will assume the role of IERC Manager to oversee Secretariat functions in situations where direct supervision by IERC Chair is not possible. 2. Added responsibilities of the SLMC-IERC Manager 3. Added specific roles for the Secretariat tasks 4. Updated References 5. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: MANAGEMENT OF INITIAL SUBMISSIONS	SLMC-IERC SOP No.: SOP No. 2

2. MANAGEMENT OF INITIAL SUBMISSIONS

The St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC) mandates the submission of a complete and specified set of documents for an application to be eligible for ethical review. A preliminary assessment will determine whether a research proposal is exempt from review or requires expedited or full board review, in accordance with the National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022 on the research ethics review process.

Any amendments to a protocol previously exempted from ethical review must be submitted for a new preliminary evaluation. This step is essential to determine if the revisions impact the risk level or otherwise alter the exemption status of the research. Such vigilance ensures ongoing compliance with ethical standards and maintains the integrity of research practices at St. Luke's Medical Center.

SOP 2. Management of Initial Submissions

- SOP 2.1 Initial Protocol Submission
- SOP 2.2 Management of Single Joint Research Ethics Board (SJREB) Reviews
- SOP 2.3 Withdrawal of Submission

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SOP Title: Initial Protocol Submission	SLMC-IERC SOP No.: SOP No. 2.1

2.1.1 PURPOSE

The purpose of this SOP is to provide a standard process in managing initial submissions of research protocols for review and approval of the SLMC-IERC.

2.1.2 SCOPE

This SOP covers the process from receipt of the research protocol documents to documentation of the submissions.

2.1.3 WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receipt of clinical trial or clinical research protocol documents		
1. Receive protocol dossier from CCT (for sponsor-initiated) or ISRC (for investigator-initiated) via email.	SLMC-IERC Submissions Processor	1 working day
Step 2. Evaluation of completeness of submitted protocol documents		
1. Check dossier completeness using SLMC-IERC Form #02C.	SLMC-IERC Submissions Processor	1 working day
2. If dossier is incomplete, notify PI/Project Leader of missing items; reject submission.	SLMC-IERC Submissions Processor	1 working day
3. If dossier is complete, assign EC Reference Number.	SLMC-IERC Submissions Processor	1 working day
4. Log protocol submission to SLMC-IERC electronic Protocol Database.	SLMC-IERC Submissions Processor	1 working day

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
5. Forward dossier and Initial Review Form to Chair (<i>SLMC-IERC Form # 02D</i>) and 2 Members-in-Charge of Screening Review and Risk Assessment.	SLMC-IERC Submissions Processor	1 working day
Step 3. Preliminary Review for Research Classification and Risk Assessment		
1. Assess if activity qualifies as research based on DHHS/FDA definitions.	SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment	Within 2 working days of receiving dossier
2. Determine if research involves human participants.	Members-in-Charge of Screening Review and Risk Assessment	Within 2 working days
3. Determine review type: full board, expedited, or exempt.	Members-in-Charge of Screening Review and Risk Assessment	Within 2 working days
4. Assess risk level (Minimal, Moderate, High).	Members-in-Charge of Screening Review and Risk Assessment	Within 2 working days
5. Submit completed Initial Review Forms via email to Secretariat.	Members-in-Charge of Screening Review and Risk Assessment	Within 2 working days
6. Forward recommendations to SLMC-IERC Chair.	SLMC-IERC Initial Submissions Coordinator	Within 1 working day of receiving forms
7. Review recommendations and make final decision on review type and risk level.	SLMC-IERC Chair	Within 1 working day of receiving recommendations

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 4. Documentation		
1. Create digital file folder for the new protocol submission.	SLMC-IERC Submissions Processor	Within 1 working day of dossier acceptance
2. File Initial Review results and documents in the digital folder.	SLMC-IERC Submissions Processor	Within 1 working day of each received document
3. Finalize entries in the electronic Protocol Database.	SLMC-IERC Submissions Processor	Upon completion of Steps 1–3

2.1.4 PROCEDURES

Step 1. Receipt of Clinical Trial or Clinical Research Protocol Documents for Review

1. The SLMC-IERC Submissions Processor shall receive the complete protocol dossier at the SLMC-IERC Office from the Center for Clinical Trials (CCT) for sponsor-initiated clinical trials and clinical research studies and from the Institutional Scientific Review Committee (ISRC) for investigator-initiated clinical research studies via email.
 - a) The protocol dossier for investigator-initiated research studies (IiT) or Administrative or Operational Research studies should include the following:
 - i. Endorsement from the Institutional Scientific Review Committee (ISRC)
 - ii. Letter of Intent addressed to the SLMC-IERC Chair
 - iii. Soft copy of the Protocol which include the following attachments:
 - Informed Consent Forms (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.) or Application of Waiver of Informed Consent (SLMC-IERC Template #02) when obtaining informed consent is truly not feasible and the research has the potential for significant benefit to society or research involves reviewing anonymized medical records or collecting data through anonymous surveys
 - Data collection forms or case report forms
 - Questionnaires (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)

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- Other related study materials (e.g. Advertisement)
 - Curriculum Vitae (CV) of Investigators and study team members
 - GCP Certificates of Investigators and study team members, preferably taken locally in a face-to-face training course; Signed attestation stating they completed the online GCP training program offered by other institutions.
 - SLMC-IERC Form # 01C Disclosure of Conflict of Interest FORM for Study Team
 - SLMC-IERC Form # 02A Initial Submission Form for Clinical Research/Trial
 - SLMC-IERC Form # 02B Checklist of Clinical Trials Initial Submission
 - SLMC-IERC Form #02C Initial Protocol Review Acknowledgment Form
- b) The protocol dossier for sponsor-initiated clinical research studies (SiT) should include the following:
- i. Letter of intent addressed to SLMC-IERC Chair
 - ii. Checklist of Clinical Trials Initial Submission (SLMC-IERC Form # 02B)
 - iii. Soft copy of the Protocol which include the following attachments:
 - Informed Consent Forms (English and Filipino with Certificate of Filipino translation); the mobile number of the Principal Investigator should be included in the ICF, Patient Card and Patient Diary aside from the clinic's phone number.
 - Case Report Forms
 - Investigator's Brochure
 - Certificate of Insurance and Insurance Policy
 - Subject Worksheets/Patient Diary/Alert Cards (English and Filipino versions)
 - Questionnaires (English and Filipino Versions)
 - Philippine Food and Drug Administration Approval (Provide a certificate from PFDA if not applicable)
 - Pharmacokinetics
 - Certificate of Product Registration in the Philippines for Post Marketing Surveillance Studies (PMSS)
 - Other related study materials (e.g. Advertisement)
 - Curriculum Vitae (CV) of Investigators and study team members
 - GCP Certificates of Investigators and study team members, preferably taken locally in a face-to-face training course; Signed attestation stating they completed the online GCP training program offered by other institutions.

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- SLMC-IERC Form # 01C Disclosure of Conflict of Interest FORM for Study Team
- Updated PRC License of Investigators and Sub-Investigators
- Delegation of Authority from the Sponsor
- License to operate to conduct a clinical trial
- SLMC-IERC Form # 02A Initial Submission Form for Clinical Research/Trial
- SLMC-IERC Form # 02B Checklist of Clinical Trials Initial Submission
- SLMC-IERC Form #02C Initial Protocol Review Acknowledgment Form

Step 2. Evaluation of completeness of the dossier based on the Initial Protocol Review Acknowledgement Form from ISRC and CCT (SLMC-IERC Form # 02C).

1. If the dossier is incomplete, the SLMC-IERC Submissions Processor shall not accept the submission and communicate with the Principal Investigator (PI)/Project Leader about the missing elements or documents.
 - a) For protocols only awaiting approval from the PFDA, the SLMC-IERC can conduct a parallel review; however, the issuance of Ethical Clearance shall be withheld until completion of said requirement.
2. If the dossier is complete, the SLMC-IERC Submissions Processor shall assign an EC Reference Number to the new protocol submission. The EC Reference Number follows the format "SL-<current year><running number>" (e.g., SL-240001). "<current year>" represents the year the dossier is submitted, and "<running number>" is a unique sequential number assigned by the SLMC-IERC Secretariat starting from 1 each year.
3. The SLMC-IERC Submissions Processor shall log the protocol submission to the SLMC-IERC electronic Protocol Database.
4. The SLMC-IERC Submissions Processor shall send the dossier and Initial Review Form (SLMC-IERC Form # 02D) to the SLMC-IERC Chair and two (2) designated Members-in-Charge of Screening Review and Risk Assessment within one (1) working day.

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Step 3. Preliminary Review of Protocols for Type of Review and Level of Risk

1. The SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment will jointly evaluate the protocols to assess whether the activity in the submitted protocol involves research. The activity is considered research if any of the following criteria is met:
 - The activity in the submitted protocol is a systematic investigation (including research development, testing and evaluation) *[DHHS Definition of Research]*
 - The activity in the submitted protocol is designed to develop or contribute to generalizable knowledge *[DHHS Definition of Research]*
 - The activity in the submitted protocol is an experiment that involves a test article and one or more human subjects that requires prior submission or for which the results are intended to be submitted later to or held for inspection by the FDA as part of an application for a research or marketing permit. *[FDA Definition of Clinical Investigation]*
2. If the activity in the submitted protocol is research, the SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment shall determine whether the research involves human participants. The research involves human participants if any of the following criteria is met:
 - Data being obtained is about one or more living individuals *[DHHS Definition of Human Subject]*
 - Data collected is through an intervention (physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes) or interaction (communication or interpersonal contact between investigator and subject) with the individual *[DHHS Definition of Human Subject]*
 - Identifiable private information is being obtained. Private identifiable information includes behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. medical record. *[DHHS Definition of Human Subject]*. Note: Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

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- The project involves an individual (either a healthy human or a patient) who is or becomes a participant in research, either as a recipient of the test article or as a control [FDA Definition of Human Subject]
 - The project involves an individual (in normal health or with a medical condition or disease) who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control [DHHS Definition of Human Subject]
3. After it has been determined that the research involves human participants, the SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment shall determine if the protocol is for full board review, expedited review, or exempt from review.
- a) Should the Members-in-Charge of Screening Review and Risk Assessment determine that a protocol meets the criteria for exemption in accordance with SOP No. 3.1, it will be documented as exempt from review.
 - b) All research protocols involving human participation shall undergo full board review unless they qualify for an expedited review as specified in SOP No. 3.2.
4. The SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment will assess the risk level of the research protocol as follows:
- **High Risk** - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution. The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.
 - **Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.
 - **Minimal risk** - if the consequences can be dealt with by routine operations; the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

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5. The SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment shall submit their accomplished Initial Review Forms to the Secretariat via email within two (2) working days of receipt of protocol dossier.
6. The SLMC-IERC Initial Submissions Coordinator shall forward the recommendations of the SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment to the SLMC-IERC Chair via email within one (1) working day.
7. The SLMC-IERC Chair shall review the recommendations and make the final decision on the type of review and level of risk.

Step 4. Documentation

1. The SLMC-IERC Submissions Processor shall create a digital protocol file folder exclusive for the new protocol submission.
2. The SLMC-IERC Submissions Processor keep the results of the Initial Review and related documents in the digital protocol file folder.
3. The SLMC-IERC Submissions Processor shall complete the SLMC-IERC electronic Protocol Database of the initial protocol submission.

2.1.5 REFERENCES

- Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.
- Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.

---Nothing Follows---

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

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SOP Title: Initial Protocol Submission		SLMC-IERC SOP No.: SOP No. 2.1

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors; Improvement of processes 1.Change in SOP number 2.Receipt of submissions via email 3.Addition of procedures on determination of type of review and level of risk by Members-in-Charge of Screening Review and Risk Assessment 4.Transfer of designation of reviewers to SOP 3.3 Full Board Review and SOP 3.2 Expedited Review 5.Creation of new Initial Review Form (SLMC-IERC Form # 02D) 6.Renumbering of Forms 7.Identification of SLMC-IERC Secretariat in charge 8.Updated list of references 9.Change of Flowchart to workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Research Protocols for SJREB Review	SLMC-IERC SOP No.: SOP No. 2.2

2.2.1. PURPOSE

The Department of Health (DOH) established the Single Joint Research Ethics Board (SJREB) through Administrative Order 2017-0021 and Administrative Order 2019-0049. These mandate the standardization of multi-site review through a single joint review conducted for the approval of multi-site research participated in by identified sites where the protocol will be implemented. An SJREB review is mandatory for all DOH hospital IERCs, although non-DOH IERCs may participate during the review.

The ethical review of protocols involving several sites may be done as a joint review of a group of PHREB accredited RECs, such as the DOH Single Joint Research Ethics Board (SJREB), provided that the review is conducted according to SOPs approved by PHREB.

This SOP outlines the procedures followed by the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC) Secretariat for managing research protocols submitted for joint review in SJREB. It aims to ensure efficient receipt, processing, and preparation of SJREB submissions, facilitating collaboration between the SLMC-IERC and the SJREB.

2.2.2. SCOPE

This SOP covers the process from receiving SJREB submissions by the SLMC-IERC Secretariat to communicating the final SLMC-IERC decision to the SJREB.

2.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receiving Initial Submissions		
1. Receive complete protocol dossier from CCT via email	SLMC-IERC Submissions Processor	
2. Verify if the protocol was previously reviewed by SLMC-IERC	SLMC-IERC Submissions Processor	Within 2 working days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
a) If previously reviewed by SJREB, request SJREB meeting minutes and approval documents	SLMC-IERC Submissions Processor	Within 2 working days
3. Assign EC Reference Number (per format in SOP Step 2.2) and attach SJREB Code	SLMC-IERC Submissions Processor	Within 2 working days
4. If SLMC-IERC was the initial reviewer, provide SLMC-IERC documentation to SJREB (meeting minutes and/or Notice of Action or Ethical Clearance)	SLMC-IERC Submissions Processor	Within 2 working days
5. Inform the SLMC-IERC Chair of the joint review protocol	SLMC-IERC Initial Submissions Coordinator	Within 2 working days of receipt
6. Assign SLMC-IERC Primary Reviewer (same reviewer involved in initial review or with relevant expertise)	SLMC-IERC Chair	Within 2 working days of notification
7. Send protocol dossier and SJREB Assessment Forms to Primary Reviewer	SLMC-IERC Initial Submissions Coordinator	Within 2 working days of assignment
8. Send Letter of Intent to SJREB Secretariat	SLMC-IERC Initial Submissions Coordinator	Within 2 working days of assignment
9. Notify Primary Reviewer of SJREB meeting schedule via email and SMS	SLMC-IERC Initial Submissions Coordinator	As soon as schedule is confirmed
Step 2. Documentation		
1. Maintain all records of SJREB joint review in the digital protocol folder	SLMC-IERC Submissions Processor and Coordinator	Continual
2. Update the SLMC-IERC protocol database with submission details	SLMC-IERC Submissions Processor and Coordinator	Within 2 working days of activity

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SOP Title: Management of Research Protocols for SJREB Review	SLMC-IERC SOP No.: SOP No. 2.2

2.2.4. PROCEDURES

Step 1. Receiving Initial Submissions

1. The SLMC-IERC Submissions Processor shall receive via email the complete protocol dossier from the Center for Clinical Trials (CCT) (see SLMC-IERC SOP No. 2.1 Step 1.b.iii)
2. The SLMC-IERC Submissions Processor shall check if the protocol has undergone prior review by the SLMC-IERC.
 - a) When a research protocol has been previously reviewed by the SJREB, the SLMC-IERC shall request a copy of SJREB's meeting minutes and approval documentation.
3. The SLMC-IERC Submissions Processor shall assign an EC Reference Number to the protocol in accordance with SOP No. 2.1 Step 2.2.
 - a) If the protocol underwent prior review by the SJREB, the SJREB Code will be attached to the EC Reference Number with a forward slash ('/') separating the two codes. (e.g., SL-240001/SJREB-2024-01).
 - b) If the protocol underwent prior review by the SLMC-IERC, the SJREB Code will be added to the EC Reference Number as described in Step 1.3.a above.
4. If the SLMC-IERC reviewed the research protocol prior to SJREB review, the SLMC-IERC shall provide SJREB with a copy of the SLMC-IERC meeting minutes and/or Notice of Action or Ethical Clearance.
5. The SLMC-IERC Initial Submissions Coordinator shall inform the SLMC-IERC Chair of the research protocol for joint review via email within two (2) working days of receipt of complete protocol dossier
6. The SLMC-IERC Chair shall assign an SLMC-IERC Primary Reviewer to provide expertise and review the submission with consideration to the SLMC-specific context.
 - a) If the protocol underwent prior review by the SLMC-IERC, the Chair will assign the same Primary Reviewer involved in the initial review.
 - b) If the protocol underwent prior review by the SJREB, the Chair will consider assigning a Primary Reviewer with relevant expertise to facilitate a smooth joint review process.
7. The SLMC-IERC Initial Submissions Coordinator shall send the protocol documents and SJREB Assessment Forms to the SLMC-IERC Primary Reviewer via email.
8. The SLMC-IERC Initial Submissions Coordinator shall send a Letter of Intent to join the SJREB meeting to SJREB Secretariat via email
9. The SLMC-IERC Initial Submissions Coordinator shall inform the SLMC-IERC Primary Reviewer of the date and time of the SJREB meeting via email and SMS (e.g. Viber).

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Step 2. Documentation

1. The SLMC-IERC Submissions Processor and Coordinator shall maintain comprehensive records of all SJREB protocol dealings, including reviewer assignments and communications in the digital file folder.
2. The SLMC-IERC Submissions Processor and Coordinator shall update the SLMC-IERC Protocol database.

2.2.5. REFERENCE

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothings Follows—

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
0	03-2024 12-2024			New SOP in compliance with suggestions of FERCAP/PHREB surveyors	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Withdrawal of Submission	SLMC-IERC SOP No.: SOP No. 2.3

2.3.1. PURPOSE

The purpose of this SOP is to establish a formal process for the withdrawal of a research protocol application by the Principal Investigator (PI) or Project Leader from the SLMC-IERC review process. This procedure ensures that all withdrawal requests are handled with clarity and efficiency while maintaining proper documentation and compliance with ethical guidelines.

2.3.2. SCOPE

This SOP It outlines the steps from receipt of Withdrawal of Application to archiving of withdrawn protocol documents.

2.3.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receive Withdrawal of Application via email	SLMC-IERC Initial Submissions Coordinator	
Step 2. Document Withdrawal Application in SLMC-IERC database	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
Step 3. Notify SLMC-IERC Chair and assigned primary reviewer(s) of the Withdrawal Application	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
Step 4. Acknowledge Withdrawal Application in writing	SLMC-IERC Chair	Within 3 working days
Step 5. Include the Withdrawal Application in the agenda of the next Full Board meeting	SLMC-IERC Initial Submissions Coordinator	Before next Full Board meeting
Step 6. Archive the withdrawn protocol documents	SLMC-IERC Initial Submissions Coordinator	Following Full Board meeting

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2.3.4. PROCEDURES

- Step 1. A Principal Investigator (PI) or Project Leader may request the withdrawal of their application at any stage before a final decision by SLMC-IERC is rendered. This request must be submitted in writing to the SLMC-IERC Initial Submissions Coordinator via email.
- Step 2. The SLMC-IERC Initial Submissions Coordinator shall document the withdrawal application via email in the SLMC-IERC database within two (2) working days.
- Step 3. The SLMC-IERC Initial Submissions Coordinator notify the Chair and the assigned primary reviewer(s) of the withdrawal application via email within two (2) working days.
- Step 4. The SLMC-IERC Chair shall acknowledge the withdrawal application in writing, specifying that the application shall not undergo further review and shall be archived accordingly three (3) working days
- Step 5. The SLMC-IERC Initial Submissions Coordinator shall include the withdrawal application in the agenda of the next Full Board meeting to ensure no further review actions are taken.
- Step 6. The SLMC-IERC Initial Submissions Coordinator shall archive the withdrawn protocol documents in accordance with SOP No. 5.4.

2.3.5. REFERENCES

- Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.
- Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothings Follows—

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory		Revision Effective Date: April 1, 2025
SOP Title: Withdrawal of Submission		SLMC-IERC SOP No.: SOP No. 2.3

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
0	03-2024 12-2024			New SOP in compliance with suggestions of FERCAP/PHREB surveyors	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: TYPES OF REVIEW	SLMC-IERC SOP No.: SOP No. 3

3. TYPES OF REVIEW

The SLMC-IERC is committed to ensuring the ethical integrity of clinical research through diligent and structured review processes. Our policy encompasses diverse types of review, tailored to the specific risks and nuances of each protocol. Each protocol is assessed with rigor to ensure compliance with ethical standards.

SOP 3 outlines the following procedures:

- SOP 3.1 Exemption from Review of Protocols
- SOP 3.2 Expedited Review of Protocols
- SOP 3.3 Full Board Review of Protocols
- SOP 3.4 Review Process for SJREB Submissions
- SOP 3.5 Preparation of Notice of Action (NOA) or Ethical Clearance (EC)
- SOP 3.6 Review of Protocols that Require Revisions after Initial Review
- SOP 3.7 Review of Clinical Trials Related to Public Health Emergencies
- SOP 3.8 Management of Appeals of Committee Decisions
- SOP 3.9 Management of Queries and Complaints

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SOP Title: Exemption from Review of Protocols	SLMC-IERC SOP No.: SOP No. 3.1

3.1.1. PURPOSE

The purpose of this SOP is to describe the criteria for exempting clinical research protocols from SL-IERC review and the process of exempting research protocols from review.

3.1.2. SCOPE

This SOP covers the process from confirmation of exemption from review to filing of documents in the research protocol file binder.

3.1.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Determine if the submitted research protocol qualifies for exemption from review	SLMC-IERC Chair	Upon completion of Screening Review
Step 2. Prepare Letter of Exemption from Review (SLMC-IERC Template # 03A)	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
Step 3. Forward the Letter of Exemption from Review to the SLMC-IERC Chair for review and signature via email.	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
Step 4. Send signed Letter of Exemption from Review to Principal Investigator/ Project Leader via email	SLMC-IERC Initial Submissions Coordinator	Within working days from Chair's approval
Step 5. File a copy of the signed Letter of Exemption from Review in the digital protocol file folder	SLMC-IERC Initial Submissions Coordinator	Within 2 working days from issuance
Step 6. Log the submission and update the SLMC-IERC electronic Protocol Database	SLMC-IERC Initial Submissions Coordinator	Within 2 working days from issuance

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SOP Title: Exemption from Review of Protocols	SLMC-IERC SOP No.: SOP No. 3.1

3.1.4. PROCEDURES

Step 1. After the SLMC-IERC Members-in-Charge of Screening Review and Risk Assessment have determined the type of review and level of risk as outlined in SOP 2.1 Step 3.4, the SLMC-IERC Chair finalizes the review of the persons designated to review exempt protocols. The SLMC-IERC Chair shall refer to the following criteria for exemptions from review based on the National Ethical Guidelines on Health and Health-Related Research (2022):

- Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., systematic and meta-analysis protocols)
- Case studies or case reports that do not involve the use of articles (e.g., drugs, devices, biologics) that have not been approved for use in humans
- Protocols that do not involve more than minimal risks or harms, such as those that are for:
 - i. institutional quality assurance purposes
 - ii. evaluation of public service programs
 - iii. public health surveillance
 - iv. educational evaluation activities
 - v. consumer acceptability tests
- Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
 - a) There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at
 - b) risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; and
 - c) The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
- Protocols that involve the use of publicly available data or information.
- Retrospective case report or study with no personal identifiers of the patient
- Database will be used primarily for clinical care or hospital operations purposes

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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Step 2. A Letter of Exemption from Review (*SLMC-IERC Template # 03A*) shall be prepared by the SLMC-IERC Initial Submissions Coordinator within two (2) working days from confirmation that study is exempt from review.

Step 3. The Letter of Exemption from Review shall be forwarded by the SLMC-IERC Initial Submissions Coordinator to the SLMC-IERC Chair for review and signature via email.

Step 4. The SLMC-IERC Initial Submissions Coordinator send the Letter of Exemption from Review to the Principal Investigator/Project Leader via email within two (2) working days from approval.

Step 5. The SLMC-IERC Initial Submissions Coordinator shall keep the copy of the Letter of Exemption from Review and related protocol documents in the digital protocol file folder.

Step 6. The SLMC-IERC Initial Submissions Coordinator shall log the submission (refer to SOP 2.1 Step 2.3) and update the SLMC-IERC electronic Protocol Database.

3.1.5. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—*Nothings Follows*—

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
				New SOP as recommended by PHREB and FERCAP surveyors			
1	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
2	03-2024 12-2024		1	Compliance with suggestions of FERCAP/PHREB surveyors 1. Change of SOP No. from 2.3 to 3.1 2. Change of Template No. from 17 to 3A 3. Identification of the SLMC-IERC Secretariat in charge 4. Inclusion of timelines 5. Update of References 6. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Expedited Review of Protocols	SLMC-IERC SOP No.: SOP No. 3.2

3.2.1. PURPOSE

The purpose of this SOP is to describe the criteria for classifying clinical research protocols for expedited review and the process of expedited review of protocols.

3.2.2. SCOPE

This SOP defines the process for expedited review of clinical research protocols from confirmation of eligibility for expedited review to documentation.

3.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Confirmation of expedited review eligibility		
1. Evaluate if protocol is qualified for expedited review	SLMC-IERC Members-in-Charge of Evaluating Initial Submissions, Chair	Within 2 working days of submission
Step 2. Designation of SLMC-IERC Primary Reviewer(s)		
1. Designate at least one (1) SL-IERC Member to conduct expedited review	SLMC-IERC Chair	Within 2 working days
2. Invite a Subject Matter Expert or External/Independent Consultant to evaluate protocol	SLMC-IERC Chair	Within 2 working days (if needed)
3. Assign a Lay Member to review the ICF	SLMC-IERC Chair	Within 2 working days (if needed)

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Distribution of Protocol Documents and Reviewer Materials		
1. Distribute protocol and reviewer materials to designated reviewers via email	SLMC-IERC Initial Submissions Coordinator	Within 2 working days of assignment
Step 4. Conduct of Expedited Review		
1. Review and evaluate protocol using Ethics Review Forms	SLMC-IERC Member, Lay Member, External/Independent Consultant	Within 14 working days
2. Recommend of course of action	SLMC-IERC Member, Lay Member, External/Independent Consultant	Within 14 working days
3. Submit completed Ethics Review Forms and recommendation	SLMC-IERC Member, Lay Member, External/Independent Consultant	Within 14 working days
4. Collate ISRC and IERC comments and recommendations	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
5. In the event of disagreements between the designated SLMC-IERC Reviewers regarding the approval status or required revisions for a protocol or informed consent documents: a) Review and analyze all comments from the SLMC-IERC Reviewers to understand the rationale behind each reviewer's position	SLMC-IERC Chair	Within 2 working days
b) Conduct consultation with SLMC-IERC reviewers, if needed	SLMC-IERC Chair	Within 2 working days (if needed)

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
c) Make final decision based on review and consultations	SLMC-IERC Chair	Within 2 working days
d) Refer to full board if no consensus or unresolved concerns	SLMC-IERC Chair	Within 2 working days
Step 5. Preparation of Notice of Action or Ethical Clearance in accordance with SOP No. 3.4.4.1		
1. Prepare Notice of Action (NOA) or Ethical Clearance	SLMC-IERC Initial Submissions Coordinator	Within 5 working days
Step 6. Documentation		
1. File results and related documents in digital protocol folder	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
2. Log submission and update electronic protocol database	SLMC-IERC Initial Submissions Coordinator	Within 2 working days

3.2.4. PROCEDURES

Step 1. Confirmation of Expedited Review Eligibility

1. The designated Members-in-Charge of Screening Review and Risk Assessment or the SLMC-IERC Chair shall evaluate within two (2) working days if a submitted clinical research protocol is qualified for expedited review, in accordance with SOP No. 2.1. Step 3.4. The following documents shall undergo expedited review:
 - Non-interventional clinical research protocols that entail only a minimal risk to the human participants and to the community
 - Human research participants do not belong to a vulnerable group
 - Clinical research protocols that are retrospective in data collection methodology

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Step 2. Designation of SLMC-IERC Primary Reviewer(s)

1. The SLMC-IERC Chair shall designate at least one (1) SLMC-IERC Member within two (2) working days on who will conduct the expedited review.
2. The SLMC-IERC Chair may invite a Subject Matter Expert or External/Independent Consultant to review the protocol.
3. If the protocol requires an informed consent, an SLMC-IERC Lay Member shall be assigned to review the ICF within two (2) workings day.

Step 3. Distribution of Protocol Documents and Reviewer Materials

1. The SLMC-IERC Initial Submissions Coordinator shall send the following via email to designated reviewers within two (2) days upon knowledge of designated SLMC Reviewer(s).
 - o Ethics Review Forms
 - Ethics Review Form for Protocol (SL-IERC Form # 02E) for the SLMC-IERC Primary Reviewer
 - Ethics Review Form for Protocol (SL-IERC Form # 02G) for the External/Independent Consultant
 - Ethics Review Form for Informed Consent (SL-IERC Form # 02F) for the SLMC-IERC Lay Person
 - o Full protocol documents
 - o Comments and recommendations of the Institutional Scientific Review Committee (ISRC) for investigator-initiated studies only

Step 4. Conduct of Expedited Review

1. The SLMC-IERC Reviewer(s) and Subject Matter Expert or External/Independent Consultant, if needed, shall be given 14 working days to complete the evaluate the protocol documents using the Ethics Review Forms.
2. SLMC-IERC Reviewer(s) shall recommend the course of action which may be any of the following:
 - o **Approved** - clinical research protocol and/or ICF is approved when they meet the following criteria:
 - Minimal Risk: The research involves minimal risk to participants, no greater than

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encountered in daily life or routine examinations.

- Scientific Merit: The research question is well-defined and the methodology is sound.
- Ethical Conduct: The research adheres to ethical principles and protects participant welfare.
- Informed Consent (if applicable): The informed consent document is clear, comprehensive, and understandable to the target population.
- **Deferred, with revisions** - The clinical research protocol documents have deviations from the expected format or content that can be addressed by revisions. These revisions typically involve corrections, clarifications, or improvements to the protocol, data collection tools, and/or ICF.
- **Deferred for Full Board Review** or a more in-depth evaluation of the protocol documents due to the following reasons:
 - Identification of significant risks to participants not adequately addressed in the protocol.
 - Concerns about the adequacy of informed consent procedures.
 - The research involves a vulnerable population requiring more scrutiny.
- 3. The SLMC-IERC Reviewer(s) and Subject Matter Expert or External/Independent Consultant, if needed, shall submit to the SLMC-IERC Initial Submissions Coordinator the results of the expedited review.
- 4. The SLMC-IERC Initial Submissions Coordinator shall collate the comments and recommendations of the ISRC and IERC.
- 5. In the event of disagreements between the SLMC-IERC Primary Reviewers regarding the approval status or required revisions for a protocol or informed consent documents during expedited review, the following steps shall be taken:
 - a) The SLMC-IERC Chair shall review and analyze the all comments from the Primary Reviewers to understand the rationale behind each reviewer's position.
 - b) At his/her discretion, the SLMC-IERC Chair may choose to have a brief consultation with the Primary Reviewers to clarify their comments or seek additional insights.
 - c) The SLMC-IERC Chair shall make the final decision regarding the research based on the reviewer comments, any consultations conducted, and his/her own expertise.
 - d) If the SLMC-IERC Chair is unable to reach a clear and well-supported final decision, the protocol and informed consent documents will be referred to the full board for review.

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Step 5. Preparation of Notice of Action or Ethical Clearance

1. The SLMC-IERC Initial Submissions Coordinator shall prepare a Notice of Action (NOA) (SLMC-IERC Template # 03B) if the recommendation is “Deferred with revisions” or “Deferred for full board review” or Ethical Clearance (SLMC-IERC Form # 03A) if the recommendation is “Approval” in accordance with SOP No. 3.5.

Step 6. Documentation

1. The SLMC-IERC Initial Submissions Coordinator shall keep the results and related documents in the digital protocol file within two (2) working days.
2. The SLMC-IERC Initial Submissions Coordinator shall log the submission (refer to SOP 2.1 Procedure Step 2 number 3) and update the SLMC-IERC electronic Protocol Database within two (2) working days.

3.2.5. REFERENCES

Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022



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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyor 1. Change in SOP No. from 2.2 to 3.2 2. Change in Form Numbers from: 05A to 02E; 05B to 02F; 06 to 02G; 13A to 03A 3. Change in Template Number from 08 to 03B; 3. Sending of ISRC recommendations to IERC reviewer(s) 4. Insertion of criteria for course of action 5. Insertion of procedures on disagreements between Reviewers 6. Transfer of procedures on preparation of NOA and Ethical Clearance to new SOP 3.5 7. Update of References 8. Change of Flowchart to Workflow	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Full Board Review of Protocols	SLMC-IERC SOP No.: SOP No. 3.3

3.3.1. PURPOSE

The purpose of this SOP is to describe the procedure for full board review of submitted protocols and protocol-related documents of clinical trials and other clinical research studies that involve more than minimal risk to the human participants and to the community or involve vulnerable population.

3.3.2. SCOPE

This SOP covers the procedures from designation of Primary Reviewer, Subject Matter Expert or External/Independent Consultant and Lay Member to documentation.

3.3.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Full Board Review of all research protocols involving human participation		
1. Subject to Full Board Review all research protocols that qualifies for Full Board Review	SLMC-IERC Chair	Within 2 working days upon receipt of Screening Review
Step 2. Designation of Primary Reviewer(s)		
1. Designate Primary Reviewer and, if needed, External/Independent Consultant for the review of clinical research protocol and Lay Member for the review of informed consent forms	SLMC-IERC Chair	Within 2 working days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Distribution of protocol documents and reviewer materials		
1. Email protocol documents, Ethics Review Forms, ISRC recommendations, if applicable, and Elements for Presentation during Full Board Review to designated reviewers	SLMC-IERC Initial Submissions Coordinator	At least 2 weeks before scheduled Full Board meeting
Step 4. Preliminary review of clinical research protocols before Full Board Meeting		
1. Evaluate and comment on the ethical and technical aspects of the protocol, to consider the recommendations of the ISRC on the scientific validity of the investigator-initiated studies	All Designated Reviewers	Before the Full Board meeting
2. Evaluate the Informed Consent Form (ICF) and/or Assent Form if the protocol includes children as participants.	All Designated Reviewers	Before the Full Board meeting
3. Assess risk level of the protocol	All Designated Reviewers	Before the Full Board meeting
4. Provide recommendations on protocol and ICF	SLMC-IERC Primary Reviewers SLMC-IERC Lay Member	Before the Full Board meeting
5. Invite PI for clarificatory interview during Full Board meeting, if needed	Designated Reviewer(s) and/or Chair	At least 1 week before Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 5. Meeting Preparation and Logistics		
1. Email invitation and/or virtual meeting link to SLMC-IERC Members, Subject Matter Expert or External/ Independent Consultant and/or invited PI/Project Leader	SLMC-IERC Initial Submissions Coordinator	At least 3 calendar days before Full Board meeting
Step 6. Conduct of Meeting		
1. Conduct Meeting in accordance with the sequence in the Agenda	SLMC-IERC	During the Full Board meeting
2. Sign attendance sheet / log attendance, notate "Virtual" on Attendance sheet for virtual attendees	SLMC-IERC Members and Secretariat, Initial Submissions Coordinator Subject Matter Expert or External/Independent Consultant Invited PI	Before Full Board meeting starts
3. Call the meeting to order	SLMC-IERC Chair	At start of Full Board meeting
4. Start meeting recording	SLMC-IERC Initial Submissions Coordinator	Once Full Board meeting is called to order
5. Lead invocation	Designated SLMC-IERC Member or Secretariat Staff	Once Full Board meeting is called to order
6. Determine quorum	SLMC-IERC Member-Secretary	After invocation
7. Present Tentative Agenda for approval/revision	SLMC-IERC Chair	During Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
8. Check for COI in any of the study protocols for review	SLMC-IERC Chair SLMC-IERC Members	During Full Board meeting
9. Present Minutes of the previous meeting for approval	SLMC-IERC Chair	During Full Board meeting
10. Discuss matters arising from the Minutes	SLMC-IERC Chair	During Full Board meeting
Step 7. Presentations and Discussions of Protocols and Findings		
1. Request the Primary Reviewers and/or a Subject Matter Expert or External/Independent Consultant to present the protocol summary and findings of initial protocol submissions	SLMC-IERC Chair	During Full Board meeting
2. Present the clinical research protocol focusing on specific areas of expertise, if invited	Subject Matter Expert or External/Independent Consultant	During Full Board meeting
3. Present the clinical research protocol and findings following established guidelines	SLMC-IERC Primary Reviewer	During Full Board meeting
4. Discussion of the merits of the clinical research protocol	SLMC-IERC Members, Subject Matter Expert or External/Independent Consultant if invited	During Full Board meeting
5. Share real-time minutes during discussions.	SLMC-IERC Member-Secretary	During Full Board meeting
6. Present Informed Consent Forms and assent (if applicable) and findings following established guidelines.	SLMC-IERC Lay Member	During Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
7. Discuss ethical considerations of the informed consent forms	SLMC-IERC Members	During Full Board meeting
8. Conduct clarificatory interview with PI/Project Leader if needed	SLMC-IERC Members	During Full Board meeting
9. Summarize protocol and ICF recommendations	SLMC-IERC Chair or SLMC-IERC Member-Secretary	During Full Board meeting
Step 8. Deliberation and Voting		
1. Deliberate and vote on the protocol and ICF separately (Approved, Deferred with revisions, Disapproved). - o In-Person Meetings: Raising of hands to signify decision. - o Virtual Meetings: Raising of hands to signify decision with open camera	SLMC-IERC Members	During Full Board meeting
Step 9. Full Board Review of Post Approval Submissions		
1. Request assigned SLMC-IERC Members-in-Charge to present their evaluations of post-approval submissions	SLMC-IERC Chair	After Full Board review of initial submissions
2. Discuss each submission, deliberate on its implications for participant safety, protocol compliance, and ethical acceptability, and arrive at a consensus decision.	SLMC-IERC Members	During Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 10. Adjournment		
1. Adjourn the meeting after confirmation of the date of the next regular meeting	SLMC-IERC Chair	After confirmation of the date of the next regular Full Boards meeting
2. Collect Ethics Review Forms from designated Reviewers a) Ethics Review Form for Protocol from the Primary Reviewer and, if applicable, from the Subject Matter Expert or External/ Independent Consultant b) Ethics Review Form for Informed Consent Forms from the Lay Member	SLMC-IERC Initial Submissions Coordinator	Immediately after the Full Board meeting
Step 11. Preparation of Notice of Action or Ethical Clearance		
1. Prepare Notice of Action or Ethical Clearance in accordance with SOP No. 3.5.	SLMC-IERC Initial Submissions Coordinator	Within 5 working days from the date of the Full Board meeting.
Step 12. Documentation		
1. File results and related documents in the digital Protocol File Folder	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
2. Log the submission and update the SLMC-IERC electronic Protocol Database	SLMC-IERC Initial Submissions Coordinator	Within 2 working days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Store the Minutes of the Meeting and recording in the digital Minutes of the Meeting file folder.	SLMC-IERC Initial Submissions Coordinator	Within 2 working days

3.3.4. PROCEDURES

Step 1. Full Board Review of Research Protocols Involving Human Participation

1. The SLMC-IERC Chair shall subject all research protocols involving human participation to undergo Full Board Review unless they qualify for expedited review as specified in SOP No. 3.2 Step 1 within two (2) working days.

Step 2. Designation of Primary Reviewer(s)

1. The SLMC-IERC Chair shall designate the following primary reviewers based on their expertise within two (2) working days:
 - i. SLMC-IERC Primary Reviewer - an SLMC-IERC member with relevant expertise who shall review the clinical research protocol.
 - ii. Subject Matter Expert or External/Independent Consultant (optional) - an independent expert with relevant qualifications or expertise in the specific subject matter of the research protocol. The Chair may invite a Subject Matter Expert or External/Independent Consultant only if there is no SLMC-IERC member with comparable expertise available to review the protocol.
 - iii. SLMC-IERC Lay Member - an SLMC-IERC Lay Person who shall review the Informed Consent Forms (ICFs).

Step 3. Distribution of Protocol Documents and Reviewer Materials

1. The SLMC-IERC Initial Submissions Coordinator shall send the following via email to designated reviewers two (2) weeks before the scheduled meeting:
 - i. Ethics Review Forms

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- Ethics Review Form for Protocol (SL-IERC Form # 02E) for the SLMC-IERC Primary Reviewer
- Ethics Review Form for Protocol (SL-IERC Form # 02G) for the External/Independent Consultant
- Ethics Review Form for Informed Consent (SL-IERC Form # 02F) for the SLMC-IERC Lay Person
- ii. Full protocol documents
- iii. Comments and recommendations of the Institutional Scientific Review Committee (ISRC) for investigator-initiated studies only
- iv. SL-IERC Template # 03F Elements for Presentation during Full Board Review of Clinical Research Protocols

Step 4. Preliminary Review of Clinical Research Protocols before Full Board Meeting

1. In the review of the clinical research protocols, the designated SLMC-IERC Primary Reviewer shall evaluate and give comments on the ethical and technical aspects of the protocol. He/she shall consider the comments and recommendations of the ISRC on the scientific validity of the investigator-initiated studies.
2. The SLMC-IERC Lay Member shall evaluate the Informed Consent Form (ICF). He/she shall comment on the Assent Form if the protocol includes children as participants.
3. The designated SLMC-IERC Reviewers shall make a risk assessment by checking the appropriate box as follows:
 - **High Risk** - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution. The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.
 - **Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.



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- **Minimal risk** - if the consequences can be dealt with by routine operations; the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)
- 4. The designated SLMC-IERC Reviewers shall provide his/her recommendations on the protocol and ICF.
- 5. In the event that a clarificatory interview with the Principal Investigator (PI)/Project Leader would be beneficial to address uncertainties or missing information in the protocol or informed consent documents, the designated SLMC-IERC Reviewer(s) and/or Chair shall inform the SLMC-IERC Initial Submissions Coordinator for invitation of the (PI)/Project Leader one (1) week before the scheduled SLMC-IERC meeting.

Step 5. Meeting Preparation and Logistics

1. The SLMC-IERC Initial Submissions Coordinator shall email the invitation and/or virtual meeting link (if hybrid or virtual) to the SLMC-IERC Members, Subject Matter Expert or External/Independent Consultant and/or invited PI/Project Leader at least three (3) calendar days before the meeting.
 - a) Full board reviews shall be conducted virtually using approved platforms (e.g., Google Meet, Zoom, or Microsoft Teams), face-to-face or hybrid as necessary.
 - b) SLMC-IERC Members and Secretariat may use various devices to join the meeting.
 - c) If face to face, the meeting shall be held at the R&B Conference Room, 6th East, St. Luke's Medical Center Quezon City.

Step 6. Conduct of Meeting

1. The SLMC-IERC meeting shall be conducted in accordance with the sequence as prepared in the Agenda (See SOP 5.1).
2. The SLMC-IERC Initial Submissions Coordinator shall request the SLMC-IERC Members, Subject Matter Expert or External/Independent Consultant, and Secretariat to sign the attendance sheet (*SL-IERC Template # 06 Meeting Attendance Sheet*) prior to the start of the SLMC-IERC Meeting for those physically present. For virtual attendees, attendance will

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- be recorded in the meeting recording and minutes, with a notation of "virtual" on the attendance sheet.
3. The SLMC-IERC Chair shall call the meeting to order.
 4. The SLMC-IERC Initial Submissions Coordinator shall start recording of the virtual meeting once the SLMC-IERC Chair calls the meeting to order.
 5. The invocation shall be led by a designated SLMC-IERC Member or Secretariat Staff.
 6. The SLMC-IERC Chair shall ask the Member-Secretary if there is a quorum. Quorum shall be declared if more than half of the SLMC-IERC Members are present (but not less than five), which should include the community representative (Lay Member) and one member who is independent of the institution or research site (PHREB National Ethical Guidelines for Research Involving Human Participants (2022)).
 - a) If there is a quorum, the Chair shall proceed with the meeting. Quorum during the full board meeting shall be maintained at all times.
 - b) If no quorum exists, the Chair shall declare adjournment.
 7. The SLMC-IERC Chair shall present the Tentative Agenda for approval/revision.
 8. The SLMC-IERC Chair shall ask if any SLMC-IERC Member has a conflict of interest in any of the study protocols for review. Conflict of Interest is present when an SLMC-IERC Member has affiliation with a Principal Investigator/Project Leader or Sponsor/CRO which will undermine his/her ability to make a free and independent evaluation.
 - a) If any member of the SLMC-IERC declares a conflict of interest in any of the protocols for review, the SLMC-IERC Chair/SLMC-IERC shall request the concerned Member not to participate in the decision-making of the specified protocol. Members with COI will be required to leave the room during deliberations and decision-making of the protocol.
 - b) If there is no declaration of any conflict of interest, the SLMC-IERC Chair shall proceed with the next item in the Agenda.
 9. The SLMC-IERC Chair shall present the Minutes of the previous meeting for reading and approval.
 10. The SLMC-IERC Chair shall discuss matters arising from the Minutes.

Step 7. Presentations and Discussions of Protocols and Findings

1. The SLMC-IERC Chair shall ask the Primary Reviewers and/or a Subject Matter Expert or External/Independent Consultant to present the protocol summary and their findings of

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- initial protocol submissions. The Presenters shall be asked to share their screen during the presentations.
2. If a Subject Matter Expert or External/Independent Consultant was invited, he/she shall present first, focusing on specific areas of expertise. Following their presentation, the External/Independent Consultant may stay for the SLMC-IERC Primary Reviewer's presentation and participate in the discussion. They will not participate in the deliberation and voting process.
 3. The SLMC-IERC Primary Reviewer shall present the protocol following the SL-IERC Template # 03F Elements for Presentation during Full Board Review of Clinical Research Protocols:
 - i. EC Reference Number and Protocol Title
 - ii. Principal Investigator/Project Leader
 - iii. Sponsor
 - iv. Conflict of interest of Principal Investigator/Project Leader
 - v. Social and scientific value
 - vi. Scientific validity, study design
 - vii. Fair selection of subjects
 - viii. Inclusion/exclusion Criteria
 - ix. Justification for inclusion of vulnerable subjects
 - x. Justifiable use of placebo, if applicable
 - xi. Standard of care
 - xii. Withdrawal criteria
 - xiii. Risks-benefits assessment
 - xiv. Recruitment process
 - xv. Informed Consent form
 - xvi. Insurance
 - xvii. Issues on the protocol
 4. Discussion of the merits of the clinical research protocol by the SLMC-IERC shall be done after the presentation of the SLMC-IERC Primary Reviewer, and, if invited, the Subject Matter Expert or External/Internal Consultant.
 5. The SLMC-IERC Member-Secretary shall share real-time minutes during discussions.
 6. The SLMC-IERC Lay Member shall present his/her review of the Informed Consent Forms following the review elements of the Ethics Review Form for Informed Consent.

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7. The SLMC-IERC Members shall discuss the ethical considerations and issues of the informed consents after the presentation of the SLMC-IERC Lay Member.
8. If the SLMC-IERC deems it necessary to ask the PI/Project Leader for some clarifications or additional information, the SLMC-IERC Chair may invite the PI/Project Leader to join the meeting. The PI/Project Leader shall be asked to exit the meeting after the SLMC-IERC has clarified or obtained information from him/her.
9. The SLMC-IERC Member Secretary or Chair shall summarize the recommendations on protocol, ethical considerations, and ICF during the scheduled Full Board meeting.

Step 8. Deliberation and Voting

1. The SLMC-IERC Members shall deliberate and vote on the protocol and ICF separately during the scheduled Full Board meeting. They shall cast their votes as follows:
 - a) In-Person Meetings - Members shall raise their hands to signify their decision.
 - b) Virtual Meetings - Members shall open their cameras and raise their hands to cast their votes.
 - c) Decisions will be based on the following criteria:
 - i. **Protocol:**
 - o **Approved** - clinical research protocol is approved when meets the following criteria:
 - Favorable Risk-Benefit Ratio: The anticipated benefits of the research outweigh the minimal risks to participants.
 - Equitable Subject Selection: The selection process for participants is fair and avoids bias.
 - Data Monitoring and Protection: The research plan includes adequate provisions for monitoring collected data to ensure participant safety, subject privacy and data confidentiality
 - Vulnerable Subject Protection: Additional safeguards are in place to protect the welfare of vulnerable populations participating in the research.
 - o **Deferred, Minor Revision** - The clinical research protocol has minor deviations from the expected format or content that can be addressed quickly without affecting its scientific merit or ethical conduct. These revisions typically involve corrections, clarifications, or improvements to existing information. Examples include:

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- Information on treatment and examination:
 - Minor inconsistencies in terminology used for treatment procedures.
 - Clarifying the frequency or duration of examinations.
 - Adding details about commonly used monitoring devices (non-invasive).
- Study objectives:
 - Rephrasing objectives for improved clarity or ensuring alignment with the research question.
 - Ensuring all SMART criteria (Specific, Measurable, Achievable, Relevant, and Time-bound) are met for each objective.
- Information on methodology and statistics:
 - Minor typographical errors in data collection instruments.
 - Clarifying the method for selecting the study population.
 - Justifying the sample size based on a power analysis (if applicable).
- **Deferred, Major Revision** - The clinical research protocol has substantial deviations from the expected format or content that raise significant questions about its scientific merit, ethical conduct, or feasibility. These revisions require a more in-depth review and potentially a redesign of the research approach. Examples include:
 - Information on treatment and examination
 - The proposed treatment or examination procedures raise ethical concerns (e.g., excessive risk to participants, inadequate safety precautions).
 - Lack of sufficient detail about potential risks or side effects associated with the treatment/examination.
 - Inadequately explained procedures in the informed consent documents, potentially compromising participant understanding
 - Study objectives
 - Objectives are unclear, unfeasible with the proposed methodology, or raise ethical concerns (e.g., exploiting vulnerable populations).
 - Objectives are not aligned with the research question or the chosen methodology.
 - Information on methodology and statistics

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- The proposed methodology is fundamentally flawed and not suitable to address the research questions.
- The chosen statistical methods are inappropriate for the type of data being collected, potentially leading to biased or unreliable results.
- Sample size is insufficient to yield statistically significant results.
- **Disapproved** - the clinical research protocol does not meet the necessary scientific, ethical, and safety criteria outlined in ethical guidelines. Detailed feedback outlining the reasons for disapproval will be provided to the PI/Project Leader. The PI/Project Leader may appeal and resubmitted for review after addressing the identified concerns.

ii. Informed Consent:

- **Approved** - when all the required elements of an informed consent document are present as follows:
 - Description of the Clinical Investigation: A clear and concise explanation of the research study, including its purpose, procedures, and duration.
 - Risks and Discomforts: A comprehensive explanation of potential risks and discomforts associated with participating in the research.
 - Benefits: A clear explanation of the anticipated benefits of the research for the participant and/or society.
 - Alternative Procedures or Treatments: Information about available alternative procedures or treatments outside of the research study.
 - Confidentiality and Data Privacy: A clear explanation of how participant confidentiality and data privacy will be maintained.
 - Compensation and Medical Treatments in Event of Injury: Information about any compensation or medical treatment available to participants in case of research-related injury.
 - Voluntary Participation: A clear statement that participation in the research is voluntary and participants have the right to withdraw at any time without penalty.
 - Understandable Language of the ICF: The informed consent document is written in a language understandable to the target participant population. Consideration should be given to literacy level and cultural appropriateness (refer to NEGHRIP 2022 for additional guidance).

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- Additional Elements of Informed Consent: The ICF includes information on:
 - Unforeseeable Risks: A statement acknowledging the possibility of unforeseen risks associated with the research.
 - Involuntary Termination of Subject's Participation: The conditions under which a participant's participation might be involuntarily terminated.
 - Additional Costs to Subject: Any additional costs that participants might incur as a result of participating in the research.
 - Consequences of Subject's Decision to Withdraw: The consequences of a participant's decision to withdraw from the research.
 - Providing Significant New Findings to Subjects: The process for informing participants of any significant new findings arising from the research.
 - Contact Details of PI or Project Leader and SLMC-IERC Chair: The informed consent document includes contact information for the PI or Project Leader and SLMC-IERC Chair for participants to ask questions.
- **Deferred, Minor Revision** - The informed consent document has minor deviations that can be addressed quickly. These might include:
 - Grammatical corrections: Typos, punctuation errors, or minor grammatical issues.
 - Inaccurate translation: Errors in translation for multilingual informed consent documents.
 - Missing contact person: Contact information for the PI or Project Leader or SLMC-IERC Chair is missing from the document.
- **Deferred, Major Revision** - The informed consent document has substantial deviations that require significant revisions. These revisions might include:
 - Missing elements: One or more of the required elements listed in the "Approved" section above are missing from the informed consent document.
 - Clarity and comprehensiveness: The document lacks clarity or is not comprehensive enough to ensure participants fully understand the research and can make informed decisions.
 - Misleading or deceptive information: The document contains misleading or deceptive information that could influence a participant's decision-making.

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Step 9. Full Board Review of Post Approval Submissions

1. Following the review of initial submissions, the SLMC-IERC Chair shall request the assigned Members-in-Charge to present their evaluations of post-approval submissions. Each reviewer shall summarize their assessment, followed by group deliberation and consensus-building or voting, as applicable. The following types of post-approval submissions shall be reviewed and discussed as applicable:
 - i. Protocol Amendments
 - ii. Continuing Review/Progress Report/Final Report
 - iii. Protocol Deviations and Violations
 - iv. Serious Adverse Events (SAEs)
 - v. Study Site Monitoring Visit
 - vi. Posters/Advertisement
 - vii. Continuing education, ECHO sessions/Lectures
 - viii. Other administrative matters
2. The SLMC-IERC shall discuss each submission, deliberate on its implications for participant safety, protocol compliance, and ethical acceptability, and arrive at a consensus decision.

Step 10. Adjournment

1. The SLMC-IERC Chair shall adjourn the meeting after confirmation of the date of the next regular Full Board meeting.
2. The SLMC-IERC Initial Submissions Coordinator shall collect the Ethics Review Forms for Protocol from Primary Reviewer and, if applicable, Subject Matter Expert or External/Independent Consultant and Ethics Review Form for Informed Consent Forms from Lay Member immediately after the decision and verify completeness. If the forms are incompletely accomplished, the SLMC-IERC Initial Submissions Coordinator shall request the concerned SLMC-IERC Member to complete the form. Other Members of the SLMC-IERC may accomplish the Ethical Review Forms when reviewing the protocol and ICF.

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Step 11. Preparation of Notice of Action or Ethical Clearance

1. The SLMC-IERC Initial Submissions Coordinator shall prepare a Notice of Action (NOA) (SLMC-IERC Template # 03B) if the recommendation is “Deferred with revisions” or “Deferred for full board review” or Ethical Clearance (SLMC-IERC Form # 03A) if the recommendation is “Approval” in accordance with SOP No. 3.5 within five (5) working days.

Step 12. Documentation

1. The SLMC-IERC Initial Submissions Coordinator shall keep the results and recording and related documents in the digital protocol file folder.
2. The SLMC-IERC Initial Submissions Coordinator shall log the submission (refer to SOP 2.1 Step 2.3) and update the SLMC-IERC electronic Protocol Database.
3. The SLMC-IERC Initial Submissions Coordinator shall store the Minutes of the Meeting and recording in the digital Minutes of the Meeting file folder.

3.3.5. REFERENCES

Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Office of Human Research Protections. (2016). *Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy*. U.S. Department of Health & Human Services.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022



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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO	DATE	NONE	NO.				
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyor 1. Change in SOP No. 2. Change in Form and Template Nos. 3. Inserted the following procedures: a. preliminary review of designated reviewers prior to presentation (previously SOP 3.2) b. conduct of meeting c. procedures from SOP 5.7 on virtual/hybrid meeting d. sequence of presentation and discussions e. clarificatory interview f. summarization of recommendations before voting 4. Removed voting on level of risk 5. Identification of specific SLMC-IERC Secretariat responsible 6. Transfer of procedures on preparation of NOA and Ethical Clearance to new SOP 3.5 7. Update of References 8. Change of Flowchart to Workflow	Pacifico Eric E. Calderon, MD, MBeth, MED SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Review Process for SJREB Submissions	SLMC-IERC SOP No.: SOP No. 3.4

3.4.1. PURPOSE

This SOP outlines the procedures followed by the SLMC-IERC for its participation in Single Joint Research Ethics Board (SJREB) meetings for protocols submitted for review at both the SJREB and SLMC-IERC levels.

3.4.2. SCOPE

This SOP outlines the procedures from notification of SLMC-IERC Primary Reviewers regarding SJREB meeting to updating of the SLMC-IERC Database.

3.4.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. SJREB Meeting and Review		
1. Notify SLMC-IERC Primary Reviewer of SJREB meeting schedule via email and SMS	SLMC-IERC Initial Submissions Coordinator	1 week before scheduled SJREB meeting
2. Review protocol documents using SJREB Assessment Forms	SLMC-IERC Primary Reviewer	Before the SJREB meeting
3. Attend and participate in the discussion of the protocol in the SJREB meeting	SLMC-IERC Primary Reviewer	On SJREB meeting date
Step 2. Receiving and Communicating SJREB Decisions		
1. Receive SJREB recommendations/ decision from SJREB Secretariat	SLMC-IERC Initial Submissions Coordinator	Within 1 working day of issuance

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. Forward SJREB recommendations/ decision to the SLMC-IERC Chair and Primary Reviewer via email.	SLMC-IERC Initial Submissions Coordinator	Immediately upon receipt
Step 3. SLMC-IERC Full Board Review and Communication		
1. No prior SLMC-IERC review: Present the protocol summary, findings and SJREB recommendations/decision to SLMC-IERC Full Board meeting	SLMC-IERC Primary Reviewer	During Full Board meeting
2. With prior SLMC-IERC review: Present SJREB recommendations/ decision to SLMC-IERC Full Board meeting	SLMC-IERC Primary Reviewer	During Full Board meeting
3. Communicate SLMC-IERC recommendations/decision to SJREB	SLMC-IERC Initial Submissions Coordinator	Within 1 week of Full Board meeting
Step 4. Documentation		
1. File all protocol documents and reviews in the digital file folder.	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
2. Update SLMC-IERC Database	SLMC-IERC Initial Submissions Coordinator	Within 2 working days

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3.4.4. PROCEDURES

Step 1. SJREB Meeting and Review

1. Upon receipt of schedule of meeting from the SJREB Secretariat, the SLMC-IERC Initial Submissions Coordinator shall inform the SLMC-IERC Primary Reviewer of the date and time of the SJREB meeting via email and SMS (e.g. Viber) one (1) week before the scheduled meeting.
2. The SLMC-IERC Primary Reviewer shall review the protocol documents using the SJREB Assessment Forms,
3. The SLMC-IERC Primary Reviewer shall participate in the discussion of the protocol in the SJREB meeting.

Step 2. Receiving and Communicating SJREB Decisions

1. The SLMC-IERC Initial Submissions Coordinator shall receive the SJREB recommendations/decision from the SJREB Secretariat within two (2) working days.
2. SLMC-IERC Initial Submissions Coordinator shall forward to the SLMC-IERC Chair and Primary Reviewer the SJREB recommendations/decision via email upon receiving.

Step 3. SLMC-IERC Full Board Review and Communication

1. If there was no prior SLMC-IERC review, the SLMC-IERC Primary Reviewer shall present the protocol summary and findings (as per SOP 3.3 Step 7.3), and SJREB recommendations/decision to the next full board meeting. While SJREB conducts the primary ethical review, the SLMC-IERC Primary Reviewer will focus on assessing site-specific issues such as institutional capacity, local context, and the feasibility of conducting the research at the SLMC site(s).
2. If there was prior SLMC-IERC review, SLMC-IERC Primary Reviewer shall present the SJREB recommendations/decision to the next full board meeting.
3. SLMC-IERC Initial Submissions Coordinator shall send the SLMC-IERC recommendations/decision to SJREB within one (1) week after the relevant full board meeting.

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Step 4. Documentation

1. The SLMC-IERC Initial Submissions Coordinator shall file all protocol documents and reviews in the digital file folder within two (2) working days.
2. The SLMC-IERC Initial Submissions Coordinator shall update the SLMC-IERC Protocol database within two (2) working days.

3.4.5. REFERENCE

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
0	03-2024 12-2024			New SOP in compliance with suggestions of FERCAP/PHREB surveyors	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP Title: Preparation of Notice of Action (NOA) or Ethical Clearance (EC)	SLMC-IERC SOP No.: SOP No. 3.5

3.5.1. PURPOSE

This SOP describes the procedures for preparing the Notice of Action (NOA) or Ethical Clearance (EC) documents based on the full board voting decision from SOP No. 3.2 and expedited review recommendation from SOP No. 3.3.

3.5.2. SCOPE

This SOP covers the process from preparation to documentation of NOA or Ethical Clearance.

3.5.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Preparation, and Issuance of Notice of Action (NOA)		
1. Draft Notice of Action (NOA) if the recommendation is “Deferred with revisions”, “Deferred for Full Board”, or “Disapproved” (use Template #03B)	SLMC-IERC Initial Submissions Coordinator	Within 5 working days of review
2. Send NOA to the SLMC-IERC Chair for review and signature	SLMC-IERC Initial Submissions Coordinator	After drafting NOA
3. Review and sign NOA	SLMC-IERC Chair	As soon as possible
4. Email NOA to the Principal Investigator/Project Leader	SLMC-IERC Initial Submissions Coordinator	Immediately after Chair's approval
5. Withdraw application if PI/Project Leader fails to respond within 90 calendar days	SLMC-IERC Initial Submissions Coordinator SLMC-IERC Chair	After 90 calendar days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 2. Preparation, and Issuance of Ethical Clearance		
1. If the recommendation is "Approved", Email PI/Project Leader of Approval decision and requirements for issuance of Ethical Clearance	SLMC-IERC Initial Submissions Coordinator	Within 3 working days of approval
2. Affix digital "IERC Approved" stamp with approval date on each document	SLMC-IERC Initial Submissions Coordinator	Within 3 working days upon receiving clean documents
3. Prepare Ethical Clearance	SLMC-IERC Initial Submissions Coordinator	After stamping approved documents
4. Send Ethical Clearance to the Chair for review and signature	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
5. Review and sign Ethical Clearance	SLMC-IERC Chair	As soon as possible
6. Send Ethical Clearance with attached IERC <i>Composition</i> and digitally stamped protocol documents to the PI or Project Leader via email	SLMC-IERC Initial Submissions Coordinator	Within 3 working days
Step 3. Documentation		
1) File all documents in the Protocol File Folder	SLMC-IERC Initial Submissions Coordinator	Within 3 working days
2) Update the SLMC-IERC Protocol Database	SLMC-IERC Initial Submissions Coordinator	Within 3 working days

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3.5.4. PROCEDURES

Step 1. Preparation and Issuance of Notice of Action

1. If the Recommendation to the review of initial submission protocol documents is “Deferred with revisions”, “Deferred for Full Board”, or “Disapproved”, the Secretariat shall prepare a Notice of Action (NOA) (SLMC-IERC Template #03B) to inform the PI/Project Leader of the review outcome within five (5) working days.
 - a) For deferred with revisions, the NOA will specify the specific details about the revisions required.
 - b) For deferred for full board review, the NOA will inform the PI that the study will undergo a full board review and the schedule of the review.
2. The SLMC-IERC Initial Submissions Coordinator shall send the NOA to the Chair for review and signature.
3. The Chair shall review and sign, if approved, the NOA.
4. The SLMC-IERC Initial Submissions Coordinator shall send the NOA with the attached IERC Composition (SLMC-IERC Template #03D) and Summary of Revisions (SLMC-IERC Template #03C) to the Principal Investigator/Project Leader via email once approved from Chair. Automated reminders will be set in Gmail to resend the NOA at regular intervals until an acknowledgment or response is received from the PI/Project Leader.
5. The PI/Project Leader shall be given a maximum of 90 calendar days to respond to the NOA, which includes submitting revised documents as requested. Failure to respond within the timeframe will be considered a withdrawal of the application. The submitted protocol files will be placed in the inactive file. Should the PI/Project Leader decide to continue the study, a new application shall be filed. A new EC Reference number will be assigned to the new application.

Step 2. Preparation and Issuance of Ethical Clearance

1. If the recommendation is “Approved”, the SLMC-IERC Initial Submissions Coordinator shall:
 - a) inform the Principal Investigator/Project Leader about the Approval via email within three (3) working days of approval;

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- b) send the PI or Project Leader the Principal Investigator's Responsibilities Form (*SL-IERC Template #03F*) for Conforme and request for the clean copies of all approved protocol documents:
 - Clinical research protocol
 - Informed consent forms
 - Case report forms (or data collection forms)
 - Patient materials
 - Any other study-related materials
2. Upon receiving the signed Principal Investigator's Responsibilities Form and clean copies of all protocol documents, the Secretariat shall affix a digital stamp to each pertinent document. The stamp will clearly display "IERC Approved" and the date of approval on each page.
3. The SLMC-IERC Initial Submissions Coordinator shall prepare the Ethical Clearance (SLMC-IERC Form #03A) which shall provide the following information:
 - Level of risk
 - Frequency of Continuing Review and due date of submission of report
 - Protocol title, version no. and date
 - Informed Consent Form version no. and date
 - Case Report Form or Data Collection Form version no.
 - Advertisement materials (if applicable) date
 - Patient's diary (if applicable)
 - Other Study Materials version no. and date
4. The SLMC-IERC Initial Submissions Coordinator shall send the Ethical Clearance to the Chair via email for review and approval.
5. The SLMC-IERC Chair shall review and sign, if approved, the Ethical Clearance.
6. The SLMC-IERC Initial Submissions Coordinator shall send the Ethical Clearance and with attached *IERC Composition (Template #03D)* and stamped protocol documents to the PI or Project Leader via email within three (3) working days of receipt of Conforme and clean copies of the protocol documents.

Step 3. Documentation

1. The SLMC-IERC Initial Submissions Coordinator shall keep the results and related documents in the digital protocol file.

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2. The SLMC-IERC Initial Submissions Coordinator shall update the SLMC-IERC Protocol Database.

3.5.5. REFERENCES

Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	06-2024 12-2024		1	Streamlined SOP for NOA and Ethical Clearance Preparation (Previously SOP 3.2 & 3.3) with minor revisions for clarity in section 3.4.4.1	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Review of Protocols that Require Revisions After Initial Review	SLMC-IERC SOP No.: SOP No. 3.6

3.6.1. PURPOSE

The purpose of this SOP is to describe the management, review, and approval of the responses to Notice of Action of clinical research protocols that have been previously evaluated and assessed with minor or major revisions.

3.6.2. SCOPE

This SOP covers the process from receiving responses to NOA to documentation.

3.6.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receiving and Tracking Responses		
1. Logg all NOA communications and responses in the SLMC-IERC Email Communications Tracker.	SLMC-IERC Submissions Processor	Upon receipt
2. Acknowledge receipt of response and check for completeness of documents (revised documents, clean copies, summary of revisions).	SLMC-IERC Submissions Processor	Upon receipt
3. Inform PI/Project Leader of missing documents if response is incomplete	SLMC-IERC Submissions Processor	Within 2 working days

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Review of Protocols that Require Revisions After Initial Review	SLMC-IERC SOP No.: SOP No. 3.6

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 2. Directing Responses for Review of Response to NOA	SLMC-IERC Initial Submissions Coordinator	
1. Categorize the response based on the initial review type and extent of revisions a) Expedited Initial Review or Full Board Initial Review with Minor Revisions routed for expedited review b) Full Board Initial Review with Major Revisions routed for another full board review	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
2. Forward revised protocol documents and summary of changes to the same SLMC-IERC Reviewers involved in the initial review and to ISRC (for investigator-initiated studies if needed)	SLMC-IERC Initial Submissions Coordinator	Within 2 working days
Step 3. Review of Response to Notice of Action		
1. Evaluate the revised documents in accordance with SOP No. 3.3 if full board review or SOP No. 3.2 if expedited review.	SLMC-IERC Reviewers	Within 7 working days
2. Present comments and recommendations of the designated Reviewers at scheduled Full Board Meeting (for revisions requiring full board review)	SLMC-IERC Member-in-Charge of Notice of Action	On scheduled Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 4. Communicating Decision		
1. Preparation and communicate new Notice of Action (NOA) if the revised documents require further revision	SLMC-IERC Initial Submissions Coordinator SLMC-IERC Chair	Within 3 working days after review
2. Preparation and communicate Ethical Clearance if the revised documents addressed all recommendations	SLMC-IERC Initial Submissions Coordinator SLMC-IERC Chair	Within 3 working days after review
Step 5. Documentation		
1. File all results and related documents in the Protocol File Folder	SLMC-IERC Submissions Processor and Coordinator	Within 3 working days after decision
2. Update the SLMC-IERC Protocol Database	SLMC-IERC Submissions Processor and Coordinator	Within 3 working days after decision

3.6.4. PROCEDURES

Step 1. Receiving and Tracking Responses

1. The SLMC-IERC Submissions Processor shall log all NOA communications and responses in the SLMC-IERC Email Communications Tracker.
2. Upon receiving a response from the PI/Project Leader, the SLMC-IERC Submissions Processor shall acknowledge receipt and confirm if all required documents are included:
 - o Revised protocol documents highlighting the changes
 - o Clean copy of revised documents
 - o Summary of revisions (SLMC-IERC Template No. 03C)
3. If the response is incomplete, the SLMC-IERC Submissions Processor shall promptly inform the PI/Project Leader of any missing documents and request their submission within a reasonable timeframe.



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Step 2. Directing Responses for Review of Response to NOA

- The SLMC-IERC Initial Submissions Coordinator shall categorize the response based on the initial review type (full board or expedited) and the extent of revisions within two (2) working days:
 - Expedited Initial Review or Full Board Initial Review with Minor Revisions (e.g., corrections, clarifications, or improvements to existing information as defined in SOP No. 3.3 Step 8.1.c): The revised documents shall be routed for expedited review (refer to SOP 3.3).
 - Full Board Initial Review with Major Revisions (e.g. redesign of the research approach, etc. as defined in SOP No. 3.3 Step 8.1.c). The revised documents shall be routed for another full board review (refer to SOP 3.3).
- The SLMC-IERC Initial Submissions Coordinator shall forward the revised protocol documents and summary of changes to the same SLMC-IERC Reviewers involved in the initial review, together with the Response to Notice of Action Evaluation Form (SLMC-IERC Form No. 03B). For investigator-initiated studies, the SLMC-IERC Initial Submissions Coordinator shall forward the revised documents and summary of changes to the Institutional Scientific Review Committee (ISRC), if needed, to evaluate if the revised protocol is already scientifically valid.

Step 3. Review of Response to Notice of Action

- The SLMC-IERC Reviewers shall evaluate the revisions in accordance with SOP No. 3.3 if full board review or SOP No. 3.2 if expedited review within seven (7) working days.
- For revised protocol documents that require Full Board Review, the SLMC-IERC Member-in-Charge of Notice of Action shall present the comments and recommendations of the designated Reviewers on the scheduled Full Board meeting.

Step 4. Communicating Decision

- If the revised documents require further revision, the SLMC-IERC Initial Submissions Coordinator shall prepare a Notice of Action (NOA) outlining the recommendations and send it to the PI/Project Leader (refer to SOP 3.5 for NOA preparation) within three (3) working days.

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2. If the revised documents addressed all recommendations, the SLMC-IERC Initial Submissions Coordinator will proceed with Ethical Clearance preparation (refer to SOP 3.5 Step 1 for details) within three (3) working days.

Step 5. Documentation

1. The SLMC-IERC Submissions Processor and Coordinator shall file the results and related documents in the digital protocol file folder.
2. The SLMC-IERC Submissions Processor and Coordinator shall update the SLMC-IERC Protocol Database.

3.6.5. REFERENCES

Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

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SOP Title: Review of Protocols that Require Revisions After Initial Review		SLMC-IERC SOP No.: SOP No. 3.6

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Change of SOP Number and improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
7	05-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors 1. Transfer of SOP on preparation and communication of decision to SOP 3.5 for streamlining 2. Change of SOP No. from 2.4 to SOP 3.6 3. Update of References 4. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Review of Clinical Trials Related to Public Health Emergencies	SLMC-IERC SOP No.: SOP No. 3.7

3.7.1. PURPOSE

The purpose of this SOP is to describe the procedure for the rapid review of submitted protocols and protocol-related documents of clinical trials that involve public health emergencies such as pandemics, epidemics, outbreaks. Due to the urgency of finding efficacious treatments and vaccines to address health emergencies, the SLMC-IERC must be prepared, flexible, and organized to conduct a thorough, rapid, and efficient review of the clinical trial protocols.

3.7.2. SCOPE

This SOP covers the process from receipt of protocol documents to document management.

3.7.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receipt and initial processing of clinical trial protocols related to public health emergencies		
1. Receive and check submission for completeness (including GCP certificates, insurance, PFDA approval if applicable) following procedures on SOP No. 2.1 Steps 1 and 2 via email; Conditionally accept incomplete submissions (pending GCP, insurance, PFDA)	SLMC-IERC Submissions Processor	Within 1 working day
2. Assign EC Reference No. with “/SJREB” and SJREB tracking number if it will be reviewed in SJREB	Initial Submissions Processor	Within 1 working day
3. Send soft copy of protocol dossier to SLMC-IERC Chair via email	SLMC-IERC Initial Submissions Processor	Within 1 working day

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 2. Classification of type of review, designation of reviewers, and forwarding of documents to reviewers		
1. Require clinical trial protocol to undergo full board review or expedited review if it meets the following criteria: - o Minimal risk, as defined by SLMC-IERC standards in SOP 2.1 Step 3.4. - o Submission to the DOH SJREB with the SLMC-IERC Primary Reviewer participating in the SJREB full board meeting discussion	SLMC-IERC Chair	Within 1 working day
2. Designate Primary Reviewer, Lay Member (for ICF), and if needed, SMEs/External Consultants	SLMC-IERC Chair	Within 1 working day of classification
4. Send clinical trial protocol dossier and Evaluation Forms to the designated Reviewers via email	SLMC-IERC Initial Submissions Coordinator	Within 2 calendar days
5. Acknowledge receipt of review assignment and confirm receipt of all documents.	SLMC-IERC Designated Reviewers	Immediately upon receipt
Step 3. Rapid review of clinical trial protocols		
A. For Expedited reviews		
1. Conduct expedited review following SOP No. 3.2 Expedited Review of Protocols.	SLMC-IERC Designated Reviewers	Within 7 calendar days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Rapid review of clinical trial protocols		
2. Submit comments and recommendations to the SLMC-IERC Secretariat	SLMC-IERC Designated Reviewers	Within 7 calendar days upon receipt of the protocol documents
3. Attend SJREB meeting and relay SLMC-IERC Reviewer comments.	SLMC-IERC Primary Reviewer	On SJREB meeting date
4. Send copy of the comments and recommendations to the SJREB if both SJREB and SLMC-IERC Full Board meetings are scheduled on the same date and time	SLMC-IERC Initial Submissions Coordinator	Before SJREB meeting
5. Accept SJREB decision as institutional IERC decision (if applicable)	SLMC-IERC	Upon receipt of SJREB decision
B. For Full Board reviews		
1. Schedule full board meeting	SLMC-IERC Chair	Within 5 calendar days (as feasible)
2. Conduct full board review virtually according to SOP No. 3.3 Full Board Review of Protocols	SLMC-IERC	3rd Wednesday of the month or earlier
3. Ensure quorum (5 voting members including Primary Reviewer, Lay, and Non-affiliated member)	SLMC-IERC Chair	During meeting
4. Accept written reviews for quorum even if reviewer is absent.	SLMC-IERC Chair	During meeting

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Step 4. Issuance of Notice of Action or Ethical Clearance		
1. Prepare Notice of Action or Ethical Clearance in accordance with SOP No. 3.5.	SLMC-IERC Initial Submissions Coordinator	Within 2 calendar days post-review
2. Issue NOA or Ethical Clearance	SLMC-IERC Initial Submissions Coordinator	Within 2 calendar days post-review for NOA Upon document completion for Ethical Clearance
Step 5. Conduct of continuing reviews		
1. Conduct site monitoring, review progress reports, SAEs, SUSARs, deviations, and final reports according to SOP Nos. 4.1, 4.2, 4.3, 4.5	SLMC-IERC	Per protocol timeline
Step 6. Documentation		
1. File soft copies of the documents in the digital clinical research protocol file	SLMC-IERC Initial Submissions Processor and Coordinator	Within 2 working days
2. Update the SLMC-IERC Protocol Database	SLMC-IERC Initial Submissions Processor and Coordinator	Within 2 working days

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3.7.4. PROCEDURES

Step 1. Receipt and initial processing of clinical trial protocols related to public health emergencies

1. Receipt via email, checking for completeness (including GCP certificates for investigators and study team members), assignment of EC Reference No., and logging to the SLMC-IERC Protocol Database of the clinical trial protocol dossier for public health emergencies shall be in accordance with SOP No. 2.1 Steps 1 and 2. However, the SLMC-IERC Initial Submissions Processor may conditionally accept submissions lacking specific documents (e.g. GCP certificates for investigators and study team members, Insurance policies, Philippine Food and Drug Administration (PFDA) approval (if applicable). Those documents may be submitted before issuance of Ethical Clearance.
2. The SLMC-IERC Initial Submissions Processor shall assign an EC Reference Number following the format outlined in SOP No. 2.1 Step 2.2. This reference number is followed by “/SJREB” and then the SJREB tracking number (e.g. SL-240001/SJREB 2024-01) if it will be reviewed in SJREB as outlined in SOP No. 2.2 Step 1.3.
3. The SLMC-IERC Initial Submissions Processor shall send the dossier to the SLMC-IERC Chair within one (1) working day via email.

Step 2. Classification of type of review, designation of reviewers, and forwarding of documents to reviewers

1. The clinical trial protocol shall undergo full board review. The SLMC-IERC Chair may decide to expedite the review of a clinical trial protocol if it meets one or more of the following criteria:
 - Minimal risk, as defined by SLMC-IERC standards in SOP 2.1 Step 3.4.
 - Submission to the Department of Health's Single Joint Review Ethics Board (SJREB) with the SLMC-IERC Primary Reviewer participating in the SJREB full board meeting discussion, provided there is DOH guidance on expedited review for such submissions.
2. The Chair shall designate an SLMC-IERC Primary Reviewer and, if needed, Subject Matter Expert or External/Independent Consultants for the review of the protocol. The Primary Reviewer must have knowledge of the ethical aspects of research in emergency

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situations. If the protocol includes informed consent form(s), the Chair shall designate SLMC-IERC Lay Member for the review of the ICFs.

- a) The designated Reviewers must be available to carry out a rapid and thorough review of the protocol documents.
3. The SLMC-IERC Initial Submissions Coordinator shall forward the complete protocol documents and SLMC-IERC Review Forms to the designated Reviewer(s) within two (2) calendar days via email.
4. The designated Reviewer(s), shall acknowledge the review assignment and confirm the receipt of all documents. Any missing information or clarification needed must be communicated back to the SLMC-IERC Initial Submissions Coordinator promptly.

Step 3. Rapid review of clinical trial protocols

A. For expedited reviews:

1. The designated Reviewer(s) shall conduct expedited review following SOP No. 3.2 Expedited Review of Protocols.
2. All comments and recommendations of the designated Reviewers must be submitted electronically to the SLMC-IERC Initial Submissions Coordinator within seven (7) calendar days upon receipt of the protocol submission.
3. The SLMC-IERC Primary Reviewer shall attend the SJREB meeting physically or virtually to relay the comments and recommendations of the Reviewers.
4. In the event that the SLMC-IERC full board meeting and the SJREB meetings are scheduled on the same date and time, the SLMC-IERC shall send a copy of the comments and recommendations to the SJREB before the meeting.
5. The SLMC-IERC may accept the SJREB's decision as its own institutional IERC decision.

B. For Full Board reviews:

1. Schedule of full board meeting shall be determined by the SLMC-IERC Chair. The SLMC-IERC normally conducts full board reviews during its regular meetings held on the third (3rd) Wednesday of each month. Recognizing the urgency of public health emergencies, the SLMC-IERC may convene expedited full board reviews when mandated by an authorized government agency. In such cases, the SLMC-IERC Chair shall strive to

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- schedule the review meeting within five (5) calendar days, whenever feasible, from receiving the complete clinical trial protocol dossier, as defined by the SLMC-IERC guidelines.
2. Full board reviews shall be conducted according to SOP No. 3.3 Full Board Review of Protocols. Full board reviews may be conducted virtually to ensure the safety of the SLMC-IERC Members and Secretariat. Virtual meeting shall be conducted using a secure video conferencing platform approved by the SLMC, such as Google Meet, Zoom, or Microsoft Teams.
 3. A quorum shall consist of at least five (5) voting members of the SLMC-IERC, including the designated Primary Reviewer, a Lay Member and one non-affiliated member.
 4. If a designated Reviewer submits his/her review but is unable to join the meeting, he/she will be considered as part of the quorum requirement.

Step 4. Issuance of Notice of Action or Ethical Clearance

1. Preparation of Notice of Action or Ethical Clearance shall be in accordance with SOP No. 3.5.
2. The NOA shall be issued within two (2) calendar days, while the Ethics Clearance shall be issued once all required documents have been submitted by the PI or Project Leader.

Step 5. Conduct of continuing reviews

1. The SLMC-IERC shall be responsible for site monitoring and review of progress reports, SAEs, SUSARs, protocol deviations and violations, and final report of onsite clinical trials. (Refer to SOP Nos. 4.1, 4.2, 4.3, and 4.5)

Step 6. Documentation

1. The SLMC-IERC Secretariat shall keep the soft copies of the documents in the digital clinical research protocol file.
2. The SLMC-IERC Secretariat shall update the SLMC-IERC Protocol Database.

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3.7.5. REFERENCES

Philippine Health Research Ethics Board. (2020) PHREB Resolution on the Review of Research Proposals on COVID-19. PHREB Resolution No. 20-001, Series of 2020, April 13, 2020.

Philippine Health Research Ethics Board. (2020) PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal. PHREB Resolution No. 20-003, Series of 2020, October 15, 2020.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

Pan American Health Organization. (2020) Template and operational guidance for the ethics review and oversight of COVID-19-related research, April 15, 2020.

World Health Organization. (2020). Guidance for research ethics committees for rapid review of research during public health emergencies. Geneva: World Health Organization.

--Nothing Follows--

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
				New SOP as recommended by PHREB			
1	06-2022		1	Replaced hard copies to soft copies of documents	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
2	03-2024 12-2024		2	Compliance with suggestions of FERCAP/PHREB surveyors 1. Change in Title from Review of Clinical Trials Related to Pandemic Diseases or Disease Outbreaks 2. Change in SOP No. from 2.6 to 3.7 3. Update of References	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Management of Appeals of Committee Decisions	SLMC-IERC SOP No.: SOP No. 3.8

3.8.1. PURPOSE

The purpose of this SOP is to delineate a formal mechanism for the evaluation and resolution of inquiries or appeals related to the decisions rendered by the SLMC IERC. It aims to facilitate a transparent, equitable, and consistent approach to addressing concerns from researchers, upholding the principles of due process and the right to a fair hearing.

3.8.2. SCOPE

This SOP applies to all inquiries and appeals regarding the decisions of SLMC IERC, encompassing initial submissions, ongoing study oversight, post-approval amendments, and decisions related to the closure of studies. It is applicable to all researchers under the purview of the SLMC IERC.

3.8.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Submit a written appeal with clearly stated grounds and supporting documents via email	Investigator/PI	Within 90 days from receipt of SLMC-IERC decision
Step 2. Log the appeal and check for completeness of submitted documents	SLMC-IERC Submissions Processor	Within 2 working days from receipt
Step 3. Forward the appeal documents to the SLMC-IERC Chair	SLMC-IERC Submissions Processor	Within 1 working day after verification
Step 4. Appoint an Appeal Review Panel of at least 3 non-involved SLMC-IERC members and SME, if needed	SLMC-IERC Chair	Within 5 calendar days after receipt of complete appeal
Step 5. Forward the appeal documents to the Appeal Review Panel and SME, if needed, via email	SLMC-IERC Submissions Processor	Within 3 working days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 6. Conduct a formal meeting (virtual or face-to-face) where the PI may present the appeal	Appeal Review Panel	Within 30 days from receipt of complete appeal
Step 7. Make and finalize decision on the appeal	Appeal Review Panel	Within 30 days from receipt of appeal
Step 8. Communicate the decision in writing to the PI/Project Leader	SLMC-IERC Submissions Processor	Within 3 working days after decision
Step 9. File and secure all appeal-related documents, including decision and meeting materials	SLMC-IERC Submissions Processor	Within 3 working days after decision

3.8.4. PROCEDURES

- Step 1. Investigators must submit their written appeal via email to the SLMC-IERC Secretariat within 90 days from the notification of the committee's decision. The appeal must clearly state the grounds for the appeal, which may include but are not limited to:
- Disagreement with the committee's decision or evaluation of the protocol or informed consent form.
 - A complete revision of the protocol or ICF that addresses all issues raised by the IERC
 - New evidence that was not available during the original review
 - Procedural errors in the review process, such as failure to follow established procedures or guidelines.
 - Conflict of interest that may have influenced the decision
 - Violation of ethical principles including allegations that the review process or the decision itself violated ethical guidelines.

- Step 2. Upon receipt, the SLMC IERC Submissions Processor shall log the appeal and check completeness of the soft copies of the required documents:

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- Formal Letter of Appeal clearly stating the grounds for the appeal and the specific decision being appealed
- If applicable, two copies revised protocol and/or ICF reflecting the changes made to address the issues raised by the SLMC-IERC. Once clean copy and once copy showing the changes made.
- If applicable, summary of the modifications made to the protocol or ICF
- Any additional documents that support the appeal, such as new research findings, statistical analyses, or expert opinions.

Step 3. The SLMC-IERC Submissions Processor shall forward the appeal documents to the SLMC-IERC Chair via email.

Step 4. The SLMC-IERC Chair shall appoint an Appeal Review Panel composed of at least three (3) SLMC-IERC Regular or Alternate Members who did not participate in the original decision, one of which has training and experience on the research topic. If none, a Subject Matter Expert or External/Independent Consultant may be invited. The Appeal Review Panel shall be responsible for a comprehensive review of the appeal, considering the provided documentation and the initial committee's rationale.

Step 5. The SLMC-IERC Submissions Processor shall forward the appeal documents to the Appeal Review Panel and SME, if needed, via email.

Step 6. The Appeal Review Panel shall conduct a formal meeting, either face to face or virtually, where the PI/Project Leader can present their case. The panel may also solicit further information or clarification from both the PI/Project Leader and the original SLMC-IERC reviewers.

Step 7. The Appeal Review Panel shall make a final decision within 30 days of the appeal submission.

Step 8. The decision shall be documented and communicated to the PI/Project Leader in writing. The decision of the Appeal Review Panel is considered final and binding.

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Step 9. All documents related to the appeal, including the submissions, meeting recording, and final decision, shall be securely filed and maintained by the SLMC-IERC Submissions Processor. The appeal process is confidential, and information is only disclosed to individuals directly involved in the review and decision-making process.

3.8.5. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development

—Nothing Follows—

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	03-2024 12-2024			New SOP as recommended by PHREB/FERCAP surveyors	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Management of Queries and Complaints	SLMC-IERC SOP No.: SOP No. 3.9

3.9.1. PURPOSE

The purpose of this SOP is to establish a formal process for handling both queries and complaints received by the SLMC-IERC. This SOP aims to ensure a systematic, fair, and consistent approach in addressing concerns from researchers and other stakeholders.

3.9.2. SCOPE

This SOP applies to all queries and complaints related to SLMC-IERC decisions, including protocol submissions, ongoing study oversight, post-approval amendments, and study closures.

3.9.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receiving and Handling Queries and Complaints		
1. Receive, log, acknowledge, and categorize query or complaint (procedural, ethical, or administrative)	SLMC-IERC Submissions Processor	Within 2 working days.
2. Forward queries or complaints to the appropriate SLMC-IERC Member or Secretariat Coordinator for response	SLMC-IERC Submissions Processor	Within 2 working days.
3. Respond to query with information or clarification in writing or verbally	SLMC-IERC Member or Secretariat Staff	Within 5 working days
4. For complaints: Resolve the complaint or designate a Review Committee or Panel who may gather additional information, interview involved parties, and review relevant documents if necessary.		

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
a) Resolution by Review Committee or Panel	Designated SLMC-IERC Review Committee or Panel	Within 2 weeks.
b) Discussion and resolution during a full board meeting for complaints that are of sufficient significance or complexity	SLMC-IERC	During Full Board meeting
Step 2. Documentation		
1. Prepare final decisions and resolutions document and forward to SLMC-IERC Chair for review and approval.	SLMC-IERC Submissions Processor	Within 2 working days from decision finalization
2. Review and sign complaints decision and resolution	SLMC-IERC Chair	Within 2 working days from receipt of draft
3. Send signed decision and resolution document to the complainant via email.	SLMC-IERC Submissions Processor	Within 2 working days
4. Store all related documents in Complaint and Query digital file folder	SLMC-IERC Submissions Processor	Within 2 working days
5. Update Complaint and Query Database	SLMC-IERC Submissions Processor	Within 2 working days
6. Restrict database access to authorized personnel only	SLMC-IERC Submissions Processor	Continual

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3.9.4. PROCEDURES

Step 1. Receiving and Handling of Queries and Complaints

1. The SLMC-IERC Submissions Processor shall receive, log, acknowledge and categorize the queries or complaints received via email, phone, or written communication.
 - a) Definition of terms:
 - i. Query is defined as a request for information or clarification regarding SLMC-IERC processes, decisions, or procedures.
 - ii. Complaint is defined as a formal expression of dissatisfaction concerning SLMC-IERC decisions or actions, including procedural errors or perceived injustices.
 - b) Completeness of queries or complaints information:
 - Submitter's name, contact number and/or email address
 - Clear description of query or complaint
 - Relevant attachments or documents (if applicable)
 - c) Categories the queries or complaints:
 - i. Procedural: Queries and complaints related to the adherence, execution, or understanding of established procedures and workflows within the SLMC-IERC process. This includes issues related to how procedures are followed, implemented, or interpreted.

Examples:

- Procedural Queries: Questions about the correct steps for submitting an initial protocol or amendment, clarification on the review timeline, or the proper process for reporting a serious adverse event.
 - Procedural Complaints: Complaints about delays or inefficiencies in the review process, concerns about inconsistencies in procedural handling, or issues related to the improper application of procedural rules.
- ii. Ethical: Queries and complaints concerning ethical aspects of research, such as adherence to ethical guidelines, ethical review procedures, and concerns about potential breaches of ethical standards.

Examples:

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- Ethical Queries: Questions about how ethical guidelines apply to a specific study, requests for clarification on ethical review requirements, or inquiries about the ethical considerations of a new research proposal.
- Ethical Complaints: Complaints about perceived ethical violations in research practices, concerns about ethical review processes not being followed, or allegations of unethical behavior by researchers or review committee members.

iii. Administrative: Queries and complaints related to administrative aspects of the IRB process, including record-keeping, document management, and general administrative procedures.

Examples:

- Administrative Queries: Questions about the status of a submission, requests for information about document handling, or inquiries about record retrieval.
- Administrative Complaints: Complaints about mismanagement of records, issues with the organization of submitted documents, or problems related to administrative support services.

2. The SLMC-IERC Submissions Processor shall forward the queries or complaints to the appropriate SLMC-IERC Member or Staff for response.
3. The SLMC-IERC Member or Staff shall address the query by providing the requested information or clarification within five (5) working days, either in writing or verbally, as appropriate.
4. The SLMC-IERC Chair may address the complaint or designate a review committee or panel who may gather additional information, interview involved parties, and review relevant documents, if necessary.
 - a) The designated review committee or panel shall resolve the complaint within two (2) weeks.
 - b) Certain complaints may be of sufficient significance or complexity to warrant discussion and resolution during a full board meeting. These shall be included in the agenda under 'Other Matters' to ensure thorough review and appropriate action.

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SOP Title: Management of Queries and Complaints	SLMC-IERC SOP No.: SOP No. 3.9

Step 2. Documentation

1. The SLMC-IERC Submissions Processor shall prepare the final decisions and resolutions document and forward to SLMC-IERC Chair for review and approval.
2. The SLMC-IERC Chair shall review and sign the complaints final decision and resolution.
3. The SLMC-IERC Submissions Processor shall send the final decision and resolution document to the complainant via email.
4. The SLMC-IERC Submissions Processor shall securely store and maintain all documents related to queries and complaints in the Complaint and Query digital file folder in accordance with confidentiality policies and data protection regulations.
5. The SLMC-IERC Submissions Processor shall update the electronic Complaint and Query Database.
6. Access to the Complaint and Query Database shall be restricted to authorized personnel to ensure the confidentiality and security of the information.

3.9.5. REFERENCES

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development

---Nothing Follows---

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SOP Title: Management of Queries and Complaints		SLMC-IERC SOP No.: SOP No. 3.9

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	07-2024 12-2024			New SOP as recommended by PHREB/FERCAP surveyors	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: CONTINUING REVIEW AND MONITORING OF PROTOCOLS	SLMC-IERC SOP No.: SOP No. 4

4. CONTINUING REVIEW AND MONITORING OF PROTOCOLS

The St. Luke's Medical Center Institutional Ethics Review Committee (SLMC IERC) is committed to upholding the highest ethical standards in the ongoing oversight of approved research. This SOP articulates our commitment to the continuous monitoring of all research activities under our purview to ensure that they remain ethically acceptable throughout their duration. We rigorously assess changes in the risk-benefit ratio, compliance with approved protocols, and overall conduct of the research to safeguard the rights, safety, and welfare of participants. This process reflects our dedication to maintaining public trust and confidence in the research we oversee.

SOP 4 outlines the following:

- SOP 4.1 Continuing Review (Progress/Final/Termination Report/Study Closure Report)
- SOP 4.2 Review of Serious Adverse Events/Suspected Unexpected Serious Adverse Reaction
- SOP 4.3 Review of Protocol Deviations and Violations Reports
- SOP 4.4. Review of Protocol Amendments
- SOP 4.5 Site Monitoring Visit

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SOP Title: CONTINUING REVIEW AND MONITORING OF PROTOCOLS	SLMC-IERC SOP No.: SOP No. 4

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SOP Title: Continuing Review (Progress/Final/Termination/Study Closure Report)	SLMC-IERC SOP No.: SOP No. 4.1

4.1.1. PURPOSE

The purpose of this SOP is to promote and ensure the continued ethical acceptability of an approved clinical research. This SOP describes the process of regular continuing review of Progress Report, Final Report, and Termination Report of previously approved clinical research protocol for assessing possible change in risk-benefit ratio.

4.1.2. SCOPE

This SOP covers the process from distribution of Memorandum regarding submission of Continuing Progress Report to receipt of submitted report, evaluation of the report, and issuance of Notice of Action or Approval to the Principal Investigator/Project Leader.

4.1.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Definition of Terms, Reporting Frequency, and Schedules		
1. Define and apply terms (Continuing Review, Progress Report, Final Report, Termination Report, Study Closure, Risk Levels)	SLMC-IERC	Every 2 years or as needed
2. Establish frequency of Progress Reports based on risk level: - Low/Minimal/Moderate Risk: Annually - High Risk: Semi-annually or more frequently	SLMC-IERC	Every 2 years or as needed
3. Establish reporting dates based on initial ethical clearance and review type (full board vs. expedited).	SLMC-IERC	Every 2 years or as needed

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
4. Establish schedule of subsequent Progress Report or Continuing Review dates clearance and review type (full board vs. expedited).	SLMC-IERC	Every 2 years or as needed
Step 2. Preparation of Memorandum to Principal Investigator/Project Leader		
1. Prepare Memorandum reminding the Principal Investigator/Project Leader to submit a Progress Report or Continuing Review Application	SLMC-IERC Progress Reports Coordinator	2 months before due date
2. Send Memorandum to PI/Project Leader	SLMC-IERC Progress Reports Coordinator	2 months before due date
3. Submit Progress Report or Continuing Review Application	PI/Project Leader	1 month before due date
Step 3. Receipt and Evaluation for Completeness of Continuing Review/ Progress Report Materials		
1. Receive Progress Report/Continuing Review and study materials via email.	SLMC-IERC Progress Reports Coordinator	Within 2 working days
2. Check for completeness of documents (see Form #04A content).	SLMC-IERC Progress Reports Coordinator	Within 2 working days
3. Acknowledge receipt or notify PI/Project Leader of missing documents.	SLMC-IERC Progress Reports Coordinator	Within 2 working days
4. Forward complete materials to IERC Member-in-Charge and Initial Primary Reviewer.	SLMC-IERC Progress Reports Coordinator	Within 2 working days of complete submission

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 4. Evaluation and Report of Reviewers		
1. Evaluate documents for type of review	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Within 10 working days
2. Evaluate if the report addresses all items in the Form and aligns with ethical principles outlined in 45 CFR 46.111 and NEGRIHP 2022	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Within 10 working days
Step 5. Expedited Review (if applicable)		
1. Conduct expedited review of report for studies that was a) initially approved thru expedited review b) previously approved by the SL-IERC at a full board meeting that meets the criteria outlined in the detailed procedures	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Within 30 calendar days of submission
2. Recommend course of action to be taken by the PI/Project Leader as outlined in Step 6.3	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Within 30 calendar days of submission
3. Forward the completed Continuing Review/Progress Report to the SLMC-IERC Progress Reports Coordinator via email	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Within 30 calendar days of submission
4. Report to the convened SLMC-IERC on all actions taken	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	During Full Board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 6. Full Board Review (if applicable)		
1. Conduct full board review of report of clinical research initially reviewed during a full board	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	During Full Board meeting
2. Present the progress report, summary of findings, and recommendations	SLMC-IERC Member-in-Charge of Continuing Review,	During Full Board meeting
3. Deliberate and arrive at a decision through consensus	SLMC-IERC	During Full Board meeting
4. Document details on the deliberations and actions of the Committee in the Minutes of the meeting.	SLMC-IERC Progress Reports Coordinator	During Full Board meeting
5. Forward the completed Continuing Review/Progress Report to the SLMC-IERC Progress Reports Coordinator via email	SLMC-IERC Member-in-Charge of Continuing Review, Primary Reviewer	Immediately after the meeting
Step 7. Notice of Action/Renewal of Ethical Clearance		
1. Prepare a written notification for the PI/Project Leader: a) Notice of Action (SLMC-IERC Template #03C) for any issues that require clarification or revision b) Renewal of Ethical Clearance (SLMC-IERC Template #04D) for approval to continue.	SLMC-IERC Progress Reports Coordinator	Within 7 working days post-review
2. Send the notification to the SLMC-IERC Chair for review and signature via email	SLMC-IERC Progress Reports Coordinator	Within 7 working days post-review
Step 8. Final Report/ Termination Report		
1. Submission of Final Report/ Termination Report		
a) Submission of Final Report (Form #04B)	Principal Investigator (PI) / Project Leader	Within 1 year after study completion

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
b) Submission of Termination Report (Form #04C)	PI / Project Leader	Immediately upon study termination
2. Check for completeness of Final Report/Termination Report materials	SLMC-IERC Progress Reports Coordinator	Within 2 working days from receipt
3. Forward complete documents to Member-in-Charge of Continuing Reviews	SLMC-IERC Progress Reports Coordinator	Within 2 working days from receipt
4. Final Report/Termination Report Review Process		
a) Review of Final/Termination Report for compliance with approved protocol	SLMC-IERC Member-in-Charge of Continuing Reviews	Within 30 calendar days from receipt
b) Recommend full board review of the Final Report if necessary if it meets the criteria specified in Step 8.4.b	SLMC-IERC Member-in-Charge of Continuing Reviews	Within 30 calendar days from receipt
c) Recommend course of action (e.g., closure, further info, full board review)	SLMC-IERC Member-in-Charge of Continuing Reviews	Within 30 calendar days from receipt
d) Forward review outcome and Final Report Form to SLMC-IERC Progress Reports Coordinator	SLMC-IERC Member-in-Charge of Continuing Reviews	Immediately after review completion
5. Prepare and draft notification to PI a) Notice of Action (SLMC-IERC Template #03C) for any issues that require clarification or revision before final closure. b) Approval of the Final Report allowing closure of the research file	SLMC-IERC Progress Reports Coordinator	Within 3 working days from recommendation
6. Send the notification to the SLMC-IERC Chair for review and signature.	SLMC-IERC Progress Reports Coordinator	Within 3 working days from recommendation

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
7. Review and sign notification	SLMC-IERC Chair	Within 3 working days from draft receipt
8. Send notification to PI	SLMC-IERC Progress Reports Coordinator	Within 2 working days from Chair's approval
9. Include report on the Final/Termination Report in next SLMC-IERC meeting agenda	SLMC-IERC Progress Reports Coordinator	2 weeks before the scheduled meeting
Step 9. Documentation		
1. Store Final/Termination Report and related documents in digital protocol file	SLMC-IERC Progress Reports Coordinator	Within 2 working days
2. Update protocol status in SLMC-IERC database	SLMC-IERC Progress Reports Coordinator	Within 2 working days

4.1.4. PROCEDURES

Step 1. Definition of Terms, Frequency, and Schedule of Progress Reports

1. The following terms shall be defined and used in this SOP:
 - a) **Continuing Review** - a process wherein the SLMC-IERC shall monitor and continuously review a protocol that it has approved during the life of the trial or research that the trial continues to meet ethical standards, participant safety is maintained, and any new information or developments are considered.
 - b) **Progress Report** - a detailed document submitted by the PI/Project Leader to the SLMC-IERC at specified intervals (e.g., annually, semi-annually) during the course of the trial. It serves to update the SLMC-IERC on how the trial is being conducted and ensures compliance with approved protocols and regulatory requirements.
 - c) **Final Report** - a comprehensive summary submitted upon the completion or early termination of the study. It must include study outcomes, data analysis (if available), adverse events, ethical compliance, and documentation of study closure.
 - d) **Study Termination** - the formal conclusion of an approved research study before its expected end date. This may be due to completion, safety concerns, sponsor

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decision, lack of funding, or other justifiable reasons. It requires notification to and approval by the SLMC-IERC.

- e) **Study Closure** – the administrative process of closing a study following its completion or termination. This involves submission of the final report and fulfillment of all regulatory and ethical requirements.
- f) **Levels of Risks:**
 - **High Risk** - if the study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigator/Project Leader s and/or institution. The study risk is greater than moderate due to the increased probability for generating serious adverse events. There is a high probability with occurrence of an event that is serious and prolonged or permanent occurring as a result of study participation
 - **Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.
 - **Minimal risk** - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)
2. The frequency of Progress Reports required from researchers shall depend on the assigned risk level of the study.
 - **Low/Minimal Risk:**
 - Reporting Period: Continuing review annually
 - Reporting Date: Twelve (12) months from the date of issuance of initial Ethical Clearance
 - **Moderate Risk:**
 - Reporting Period: Continuing review annually
 - Reporting Date: Twelve (12) months from the date of issuance of initial Ethical Clearance

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○ **High Risk:**

- Reporting Period: Progress report semi-annually or more frequently, based on specific conditions such as enrollment milestones or significant protocol changes and continuing review annually.
- Semi-annually or more frequent reporting based on two factors:
 - Time: Semi-annual reports are typically required, starting six (6) months from the from the date of issuance of initial Ethical Clearance
 - Enrollment: The SLMC-IERC may require a progress report upon reaching a pre-determined number of enrolled subjects, even if the six-month timeframe hasn't been reached. Whichever condition (time or enrollment) is met first triggers the report submission.

Example:

During initial review, a high-risk study is approved with a requirement for semi-annual reporting after ethical clearance. Additionally, the SLMC-IERC determines that a progress report is needed upon enrolling 10 participants. If the study enrolls 10 participants within three months of ethical clearance, the progress report would be due at that point, even though the standard semi-annual timeframe has not elapsed.

3. The designation of the date for the initial progress report or continuing review shall be based on the date when the SLMC-IERC issued the Ethical Clearance.

- Protocols approved by full board review
 - a) When the SLMC-IERC approves a clinical research without requiring changes to protocol or informed consent the effective date of the initial approval is the date of that full board meeting.
 - b) When the SLMC-IERC requires revisions, clarifications in the protocol or informed consent, or submission of additional documents, the SLMC-IERC Chair or Member-in-Charge on Continuing Review is directed to accept, review and approve the submitted materials. If found satisfactory, the initial approval date is the date when the Chair or designated member approved the submitted materials.
- Protocols approved by expedited review
 - a) Protocols approved by expedited review shall be designated to have an initial continuing review date one year after the SL-IERC Chair and designated IERC Reviewers had approved the clinical research protocol.

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4. The schedule of subsequent Progress Report or Continuing Review dates shall depend on the assessment of the immediate previous report.
 - a) If the immediate progress report is found satisfactory in terms of conduct and safety, the subsequent effective review date shall be one (1) year after the SLMC-IERC issued the Ethical Clearance.
 - b) If the immediate progress report is found with unwarranted violations, undue risks and/or unresolved safety problems, the SLMC-IERC may declare an earlier continuing review date and more frequent progress reports.
 - c) In a full board review of a progress report, the date of the convened SLMC-IERC meeting which conducted the review and approved the continuation of the study (with or without conditions) determines the latest permissible date of the next progress report or continuing review.
 - d) In an expedited review of a progress report, the date when the SLMC-IERC Chair and/or Member-in-Charge on Continuing Review approved the continuation of the study shall be the permissible date of the next progress report or continuing review.

Step 2. Preparation of Memorandum to the Principal Investigator/Project Leader

1. The SLMC-IERC Progress Reports Coordinator shall prepare a Memorandum reminding the Principal Investigator/Project Leader to submit a Progress Report or Continuing Review Application of his/her on-going clinical research (*SLMC-IERC Template # 04A*)
2. The SLMC-IERC Progress Reports Coordinator shall send the Memorandum to the PI/Project Leader two (2) months prior to the designated reporting date.
3. The PI/Project Leader shall submit the Progress Report or Continuing Review Application a month before the designated reporting date.

Step 3. Receipt and Evaluation for Completeness of Continuing Review/Progress Report Materials

1. The SLMC-IERC Progress Reports Coordinator shall receive the Continuing Review/Progress Report and study materials via email.
2. The SLMC-IERC Progress Reports Coordinator shall check the Continuing Review/Progress Report materials for completeness. The Continuing Review/Progress Report materials are the following:

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A. Continuing Review/Progress Report that includes the following: *(refer to SL-IERC Form # 04A)*

- a) List of the study team including the Principal Investigator/Project Leader with their corresponding responsibilities
- b) Status of the study
 - Study not started
 - Open Study
 - Data collection (retrospective chart review)
 - Recruiting participants
 - Not yet recruiting participants
 - Closed Study
 - Active, Not recruiting: Study ongoing, no new participants being recruited.
 - Completed: Study has ended normally.
 - Terminated: Recruitment stopped permanently.
 - Suspended: Recruitment temporarily halted.
 - Withdrawn
 - Enrolling by invitation
 - Data Analysis
 - Manuscript/Publication Phase
 - For study close-out
 - Participants
 - Enrollment Status
 - Number of participants required for this site
 - No enrollment to date
 - Screening
 - Number of participants in the screening stage
 - Enrolled Participants
 - Number of consented participants enrolled
 - Number of participants still on study drug/undergoing study procedures (e.g., lab tests, questionnaires)
 - Number of participants completed taking study drug/study procedure but currently in follow-up
 - Participant Outcomes

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- Number of participants who have been withdrawn/terminated from the study
 - Number of participants who have completed the study
 - Biological Samples (if applicable)
 - Number of biological samples utilized for a retrospective study data
- c) Informed Consent Process
 - Number of participants who signed Informed Consent Form (ICF) but failed screening.
 - Number of consented participants who discontinued before treatment/study procedures began.
 - Number of consented subjects who discontinued due to occurrence of SAE or AE
 - Number of consented participants who discontinued before trial completion.
 - Number of subjects enrolled but failed to sign consent prior to performance of any procedures
 - List the consent form(s) currently in use (e.g. main, genomics, etc.)
- d) Safety Reporting - Summary of any serious adverse events, any unanticipated problems and available information regarding adverse events.
 - Number of site SAEs
 - Number of site SUSARs
 - Summary of all ON SITE SAEs/SUSARs since initial approval which includes
 - Participant Study Number
 - Date of Onset
 - Description of SAE/SUSAR
 - Date reported to IERC
 - Study Drug Relationship
 - Outcome
 - Information if the study has been stopped, put on hold or recruitment put on hold at any site for any reason
- e) Protocol Amendments - Summary of the amendments to the research protocol and informed consent approved by the SL-IERC since the initial review or the last continuing review.

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- f) New Information – description of any new information in the literature, interim findings or preliminary results that would change the rationale, procedures, study design and/or risk benefit profile of the study since the last SLMC-IERC review.
- g) Protocol Violations/Deviations – Summary of any violations/deviations of the protocol and breaches of Good Clinical Practice since the last SLMC-IERC review.
- h) Study Monitoring Visits – Information on monitoring by the sponsor or CRO (CRM/CRA) since the last SLMC-IERC review
- i) Audit - Information on any audit done by local or foreign regulatory authorities since the last SLMC-IERC review
- B. Latest Curriculum Vitae, valid GCP Certificate and Disclosure of Conflict of Interest (signed and dated) of all the study team members
- 3. Upon receipt of complete submission, the SLMC-IERC Progress Reports Coordinator shall promptly acknowledge receipt via email. In case of incomplete submission, the Secretariat shall promptly notify the PI/Project Leader, specifying required missing documents or information.
- 4. The SLMC-IERC Progress Reports Coordinator shall forward the Continuing Review/Progress Report materials to the SLMC-IERC Member-in-Charge of Continuing Review and the SLMC-IERC member assigned as the primary reviewer in the initial submission review via email within 1-2 working days upon receipt of complete documents.

Step 4. Evaluation and Report of the SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer

1. The SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer shall evaluate all documents and choose one of two options: conduct an expedited review for low-risk studies meeting specific criteria (Step 5) or present a summary of the findings and recommendations for full board review (Step 6) for higher-risk or more complex studies.
2. The SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer shall evaluate if the Continuing Review/Progress Report address the following:
 - i. Critical issues requiring SLMC-IERC attention
 - ii. Key changes being proposed by the Investigator
 - iii. Subject enrollment rate compared to expectations
 - iv. Types and frequency of adverse events (expected or unexpected)

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- v. Subject complaints about research conduct leading to withdrawal.
- vi. Alignment of the research with ethical principles outlined in 45 CFR 46.111 and NEGRIHP 2022:
 - a. Risks to subject are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever, appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b. Risks to subject are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.
 - c. Selection of subject is equitable.
 - d. Informed consent are sought from each subject or the subject's legally authorized representative, and appropriately documented.
 - e. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - f. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - g. Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence.

Step 5. Expedited Review of Continuing Review

1. Only the reports from following clinical research studies can undergo expedited review:
 - a) initially approved thru expedited review
 - b) previously approved by the SL-IERC at a full board meeting on the following conditions:
 - i. The clinical research previously approved by full board progresses to the stage where all of the remaining human subjects research activities involve no more than minimal risk to the subjects and fall within the scope mentioned in the Expedited Review SOP
 - ii. Where the clinical research is (i) permanently closed to the enrolment of new subjects; (ii) all subjects have completed all research-related interventions and (iii) the research remains active only for long-term follow-up of subjects. Long-term follow-up includes:

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- Research interactions that involve no more than minimal risk to subjects (e.g. quality of life surveys)
- Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.
- iii. Where no subjects have been enrolled and no additional risks have been identified
- iv. Where the remaining clinical research activities are limited to data analysis.
- v. The study continues to pose no more than minimal risk to subject
- vi. There are no significant changes to the study protocol, informed consent document, or study procedures since the previous review.
- vii. The study is progressing as planned, and the investigator is in compliance with the approved protocol and regulatory requirements.
- viii. No unexpected adverse events or safety concerns have been reported that require immediate attention or modification of the study.
- 2. The SLMC-IERC Member-in-Charge of Continuing Review shall recommend course of action to be taken by the PI/Project Leader as outlined in Step 6.3.
- 3. The SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer shall forward the completed Continuing Review/Progress Report to the SLMC-IERC Progress Reports Coordinator via email within 30 calendar days of submission.
- 4. The SL-IERC Member-in-Charge or SLMC-IERC Chair shall report to the convened SL-IERC on all actions taken on the clinical research and its continuing review report that have been reviewed under the expedited procedure.

Step 6. Full Board Review of Continuing Review/Progress Report

1. The Continuing Review/Progress Report of a clinical research initially reviewed during a full board SLMC-IERC meeting shall also be reviewed by the SLMC-IERC in full board.
2. The SLMC-IERC Member-in-Charge on Continuing Review shall present the following to the full board for review and discussion:
 - Progress report of the research
 - Summary of the findings from the Continuing Review/Progress Report process
 - Recommendations including frequency of reporting of future progress reports or continuing reviews (e.g., semi-annual or annually)

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3. The SLMC-IERC full board shall deliberate on the findings and recommendations of the SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer and arrive at a decision through consensus. The actions to be taken can be any of the following:
 - Approve Continuation: The SLMC-IERC approves the research to continue without changes.
 - Request for More Information: The SLMC-IERC requires additional information from the investigator before making a decision.
 - Deferral: The SLMC-IERC postpones a decision on the research pending receipt of additional information or clarification from the investigator.
 - Suspension: The SLMC-IERC temporarily halts research activities due to safety concerns or noncompliance with the SLMC-IERC approval.
 - Termination: The SLMC-IERC permanently stops the research due to ethical concerns, safety risks, or noncompliance.
4. The SLMC-IERC Progress Reports Coordinator shall include details on the deliberations and actions of the Committee in the Minutes of the SLMC-IERC meeting.
5. The SLMC-IERC Member-in-Charge of Continuing Review and Primary Reviewer shall forward the completed Continuing Review/Progress Report to the SLMC-IERC Progress Reports Coordinator via email.

Step 7. Notice of Action/Renewal of Ethical Clearance

1. The SLMC-IERC Progress Reports Coordinator shall prepare a written notification for the Principal Investigator/Project Leader following the SLMC-IERC review. The type of notification will depend on the SLMC-IERC's decision:
 - a) Notice of Action (SLMC-IERC Template #03C) shall be used to communicate any issues identified during the review that require clarification or revision from the investigator before SLMC-IERC approval can be granted.
 - b) Renewal of Ethical Clearance (SLMC-IERC Template #04D) shall be issued to signify the SLMC-IERC's approval for the research to continue.
2. The SLMC-IERC Progress Reports Coordinator shall send the notification to the SLMC-IERC Chair for review and signature via email.
3. The SLMC-IERC Progress Reports Coordinator shall send the notification to the PI/Project Leader via email.

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Step 8. Final Report/Termination Report

1. Submission of Final Report/Termination Report

a) Final Report Submission

Upon completion of a clinical research, the PI/Project Leader shall submit a Final Report within one (1) year of the clinical research completion (*SLMC-IERC Form # 04B*) via email. The Final Report must include:

- Study status, if completed or terminated
- Reason(s) for termination (if applicable)
- Participants
 - Number of participants required for this site
 - Number of consented participants enrolled
 - Number of participants who have been withdrawn/terminated from the study
 - Number of biological samples utilized for a retrospective study data
- Any deviations from the protocol
- Any issues/problems encountered
- Research's key findings and conclusion
- Actions for dissemination of study results
- Final manuscript (for investigator-initiated studies)

b) Termination Report Submission

Upon termination of a clinical research, the PI/Project Leader shall submit a Termination Report (*SLMC-IERC Form # 04C*) via email. The Termination Report must include:

- Reason(s) for termination
- Participants
 - Number of participants required for this site
 - Number of consented participants enrolled
 - Number of participants who have been withdrawn/terminated from the study
 - Number of biological samples utilized for a retrospective study data
- Patient Safety Management
 - Actions taken to protect participants
 - Follow-up procedures for participants
 - Notification of termination to participants
 - Handling of adverse events

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- Review of safety data
 - Data Management Plan
 - Data storage procedures
 - Data security measures
 - Data retention period
 - Data destruction procedures (if applicable)
 - Plans for data sharing or publication (if applicable)
- 2. The SLMC-IERC Progress Reports Coordinator shall check the Final Report/Termination Report materials for completeness.
- 3. The SLMC-IERC Progress Reports Coordinator shall forward the Final Report / Termination Report materials to the SLMC-IERC Member-in-Charge of Continuing Reviews via email within two (2) working days of receipt of complete documents.
- 4. Final Report/Termination Report Review Process
 - a) The SLMC-IERC Member-in-Charge of Continuing Reviews shall review the Final Report/Termination Report materials submitted by the PI/Project Leader within 30 calendar days of receipt for compliance with approved protocol.
 - b) A full board review of the Final Report may be necessary if the initial review identifies any of the following:
 - Significant or unexpected findings in the Final Report/Termination Report.
 - Major protocol deviations that haven't been previously addressed by the Continuing Review process.
 - Outstanding compliance concerns regarding the research.
 - c) The SLMC-IERC Member-in-Charge of Continuing Reviews may recommend the following course of action:
 - For closure of file and archiving
 - Request further information
 - Recommend further action
 - For full board review (for expedited reviews)
 - d) The SLMC-IERC Member-in-Charge of Continuing Reviews shall forward the completed Final Report Form to the SLMC-IERC Progress Reports Coordinator.
- 5. The SLMC-IERC Progress Reports Coordinator shall prepare a written notification to the PI/Project Leader following the review. The type of notification will depend on the recommendation:

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- a) Notice of Action (SLMC-IERC Template #03C) shall be used to communicate any issues that require clarification or revision from the investigator before final closure.
- b) An email shall be sent to the PI/Project Leader signifying the SLMC-IERC's approval of the Final Report and allows for closure of the research file.
6. The SLMC-IERC Progress Reports Coordinator shall send the notification to the SLMC-IERC Chair for review and signature.
7. The SLMC-IERC Progress Reports Coordinator shall send the notification to the PI/Project Leader via email.
8. The SLMC-IERC Progress Reports Coordinator shall include a report on the Final/Termination Report in the Agenda of the next SLMC-IERC meeting for information purposes.

Step 9. Documentation

1. The SLMC-IERC Progress Reports Coordinator shall securely store the Continuing Review/Progress Reports, Final Report/Termination Report and all related documents in the digital protocol file.
2. The SLMC-IERC Progress Reports Coordinator shall update the status of the research project in the SLMC-IERC Protocol Database to reflect completion or termination.

4.1.5. REFERENCES:

- Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.111 Criteria for Approval of Research. U.S. Department of Health & Human Services.

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Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.

World Health Organization International Agency for Research. (2022). IARC Ethics Committee (IEC) Standard Operating Procedures (SOPs). Lyon: World Health Organization International Agency for Research.

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 07-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors 1. Delineation of procedures for progress reports, continuing reviews, final reports, and termination reports. 2. Identification of SLMC-IERC Secretariat in charge 3. Addition of SLMC-IERC Primary Reviewer who will evaluate the reports 4. Alignment of course of action with Form 04A. 4. Change in Form No. from 16 to 04A; 17 to 04B 5. New Form No. 04C for Termination Report 6. Change in Template No. from 15 to 0A4; 7. Update of References	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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4.2.1. PURPOSE

The purpose of this SOP is to outline the procedures for handling and assessing adverse drug reactions (ADRs), serious adverse events (SAEs), and suspected unexpected serious adverse reactions (SUSARs) that occur in human participants involved in research studies conducted in St. Luke's Medical Center. This SOP aims to ensure the safety and well-being of research participants by providing clear guidelines for the timely detection, reporting, and management of adverse events.

4.2.2. SCOPE

This SOP covers the process from receipt of safety reports of ADRs, SAEs and SUSARS until issuance of Notice of Action to Principal Investigator/Project Leader.

4.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Submission of Internal or Onsite ADR/SAE/SUSAR using ADR/SAE/ SUSAR Report Form (<i>SLMC-IERC Form # 04E</i>)		
1. Define AE, SAE, SUSAR, ADR	SLMC-IERC	Every 2 years or as needed
2. Submit of ADR/SAE/SUSAR reports via email	Principal Investigators/ Project Leaders	Within 7 calendar days for SAEs from knowledge; Within 15 calendar days for other unexpected problems from knowledge

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Receive and acknowledge ADR/SAE/SUSAR reports via email	SLMC-IERC SAE and Noncompliance Coordinator	Within 2 working days
4. Forward ADR/SAE/SUSAR reports to the SLMC-IERC Member-in-Charge of ADR/SAE/SUSAR, Primary Reviewer and Pharmacologist via email	SLMC-IERC SAE and Noncompliance Coordinator	Within 2 working days
Step 2. Submission of External or Offsite SAE/SUSAR (quarterly submission)		
1) Submit external or offsite ADRs/SAEs/SUSARs via email.	Principal Investigators/ Project Leaders	Quarterly
2) Forward summary list of the ADRs/SAEs/SUSARs to the SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR Primary Reviewer and Pharmacologist via email	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days
Step 3. Evaluation of Onsite ADR/SAE/SUSAR Report		
1) Evaluate ADR/SAE/SUSAR in terms of risk to the human subject participant	SLMC-IERC Member-in-Charge of ADR/SAE/SUSAR Primary Reviewer Pharmacologist	Within 7 working days
2) Notify the SLMC-IERC Chair If ADR/SAE/SUSAR needs immediate action as it exposes the human subject participant to risk of further harm.	SLMC-IERC Member-in-Charge of ADR/SAE/ SUSAR	Immediately after evaluation
a) Temporarily suspend the clinical research and call for emergency meeting of the full board to discuss the report and potential actions.	SLMC-IERC Chair	As soon as possible

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3) Schedule presentation of the ADR/SAE/SUSAR in the next full board meeting if no immediate action is required	SLMC-IERC Member-in-Charge of ADR/SAE/ SUSAR	Within 7 working days
4) Present ADR/SAE/SUSAR report, findings and recommendations in full board meeting	SLMC-IERC Member-in-Charge on ADR/SAE/ SUSAR	During full board meeting
5) Discuss findings and decision by voting for recommended course of action	SLMC-IERC	During full board meeting
Step 4. Evaluation of Offsite ADR/SAE/ SUSAR Report		
1) Evaluate offsite ADR/SAE/ SUSAR in terms of risk to the human subject participant	SLMC-IERC Member-in-Charge of ADR/SAE/ SUSAR Primary Reviewer Pharmacologist	Within 7 working days
2) Report offsite event summary to full board	SLMC-IERC Member-in-Charge on ADR/SAE/ SUSAR	During full board meeting
3) Consider severity, unexpectedness, and potential risks to local participants associated with the reported offsite ADRs/SAEs/SUSARs.	SLMC-IERC	During full board meeting
4) Recommend potential actions	SLMC-IERC	During full board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 5. Notification of SLMC-IERC Action		
1) Prepare notification to the PI/Project Leader regarding the recommendations: a) Notice of Action if recommended further information or measures to prevent further harm to participants b) Notice of No Action if no further action required	SLMC-IERC SAE and Noncompliance Coordinator	Within 7 working days after board decision
2) Forward notification to SLMC-IERC Chair for review and signature via email	SLMC-IERC SAE and Noncompliance Coordinator	Within 7 working days after board decision
3) Forward notification to the Principal Investigator/ Project Leader via email	SLMC-IERC SAE and Noncompliance Coordinator	Upon approval of the chair
Step 6. Documentation		
1) File ADR/SAE/SUSAR reports and copies of notifications in the appropriate digital clinical research folder and digital SAE folder.	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days
2) Log ADR/SAE/SUSAR reports in the electronic database for SAEs	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days

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4.2.4. PROCEDURES

Step 1. Submission of Internal or Onsite ADR/SAE/SUSAR using ADR/SAE/SUSAR Report Form (SLMC-IERC Form # 04E)

1. The following terms shall be defined and used in this SOP:

a) Adverse Events (AE)

- Any untoward or unfavorable medical occurrence in a human subject including any abnormal sign (e.g. abnormal physical exam or laboratory finding) symptom or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.
- Encompass both physical and psychological harms occurring commonly in biomedical research but occasionally can occur in social and behavioral research.
- Types of adverse events reported in an institution
 - i. Internal adverse events – adverse events experienced by subjects enrolled in a particular clinical trial in this institution (St. Luke's Medical Center Quezon City or Global City)
 - ii. External adverse events – adverse events experienced by subjects in other institutions/medical centers enrolled in same clinical trial as conducted in this institution

b) SAE (Serious Adverse Event/Serious Drug Experiences) as defined under 21 CFR 312.32

- An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:
 - a) Death
 - b) Disability or persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 - c) Life-threatening drug experience
 - d) Congenital anomaly/birth defect
 - e) Important medical event
 - f) In-patient hospitalization or prolongation of existing hospitalization
 - g) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

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- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.
- c) **SUSAR (Suspected Unexpected Serious Adverse Reaction):**
 - Any adverse drug experience the specificity or severity of which is not consistent with the current Investigator Brochure or with the risk information described in the general investigational plan or elsewhere in the current application. “Unexpected” as used in this definition refers to an adverse drug experience that has not been previously observed or from the perspective of the pharmacological properties of the test product is not anticipated.
- d) **Adverse Drug Reaction (ADR)** can be considered unexpected or unanticipated based on the following criteria:
 - a) Unexpected since nature of event, severity, or frequency is not consistent with either:
 - i. Known or foreseeable risks of adverse events described in the SLMC-IERC approved protocol and informed-consent document, Investigator Brochure and other relevant sources of information such as product labelling and package inserts.
 - ii. Expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
 - b) Definitely related or possibly related to participation in the research. Possibly related means there is a reasonable probability that the incident, experience or outcome may have been caused by the procedures involved in the research.
 - c) Incident or outcome of the research places subjects or others at a greater risk of harm (i.e. physical, psychological, economic or social harm that was previously known or recognized)

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2. Principal Investigators/Project Leaders shall submit ADR/SAE/SUSAR reports via email following the guidelines on submission outlined in this SOP as follows: (see related R&B Policy on Monitoring of Clinical Safety of Investigational Drugs).

a) ADR/SAE/SUSAR Reports of the PI/Project Leader should include the following:

- i. Appropriate identifying information for the clinical trial/research protocol, such as the title, Principal Investigator's/Project Leader's name, contact number, and EC Reference Number.
- ii. Subject information such as Subject number, initials, date of birth, gender, date of enrollment
- iii. Detailed description of the ADR/SAE/SUSAR, such as:
 - SAE diagnosis
 - Dates of start and end of experience
 - Date of awareness
 - SAE category as defined in Step 1
 - Severity
 - Mild
 - Moderate
 - Severe
 - Relationship to study
 - Unrelated
 - Unlikely
 - Possibly
 - Definitely
 - Expectedness
 - Expected
 - Unexpected
- iv. Investigator's narrative report, e.g. basis for determining that the ADR/SAE/SUSAR, experience or outcome represents an unexpected problem, description of any changes to the protocol or other corrective actions that have been taken or proposed in response to the unanticipated problem
- v. Type of report, outcome, reporter, date of report

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- b) Time frame in reporting adverse events to the SL-IERC
 - i. Unexpected problems that are serious adverse events should be reported to the SLMC-IERC within one (1) week (7 calendar days) of the PI becoming aware of the event
 - ii. Any other unexpected problem should be reported to the SLMC-IERC with two (2) weeks (15 calendar days) of the Principal Investigator/Project Leader becoming aware of the problem.
3. The SLMC-IERC SAE and Noncompliance Coordinator shall receive, acknowledge and date the ADR/SAE/SUSAR report via email.
4. The SLMC-IERC SAE and Noncompliance Coordinator shall forward the ADR/SAE/SUSAR report to the SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR, Primary Reviewer and Pharmacologist via email.

Step 2. Submission of External or Offsite SAE/SUSAR (quarterly submission)

1. The PI/Project Leader shall submit external or offsite ADRs/SAEs/SUSARs quarterly via email.
2. The SLMC-IERC SAE and Noncompliance Coordinator shall forward the summary list of the ADRs/SAEs/SUSARs to the SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR Primary Reviewer and Pharmacologist within three (3) working days via email.

Step 3. Evaluation of Onsite ADR/SAE/SUSAR Report

1. The SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR, Primary Reviewer and Pharmacologist shall evaluate the ADRs/SAEs/SUSARs in terms of risk to the human subject participant. The evaluation will assess the severity, relatedness to the study intervention, and potential risk to the human subject participant within seven (7) working days.
2. If ADR/SAE/SUSAR needs immediate action as it exposes the human subject participant to risk of further harm, upon complete receipt of the evaluation form the SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR will immediately notify the SLMC-IERC Chair.
 - a) The SLMC-IERC Chair may temporarily suspend the clinical research and shall call for an emergency meeting of the full board to discuss the report and potential actions.

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3. If the SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR deems that no immediate action is required, the report shall be presented in the next full board meeting.
4. During the full board meeting, SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR shall present the report, findings and recommendations.
5. The SLMC-IERC shall discuss the findings during the full board meeting and make a decision by voting for the recommended course of action:
 - a) Request further information on the ADR/SAE/SUSAR report to make a more comprehensive assessment
 - b) Recommend measures that can be undertaken to prevent further harm to subjects:
 - Changes to the research protocol to eliminate apparent immediate hazards to subjects.
 - Modification of inclusion or exclusion criteria to mitigate the newly identified risks
 - Implementation of additional procedures for monitoring subjects.
 - Suspension of enrolment of new subjects
 - Suspension of research procedures in currently enrolled subjects
 - Modification of informed consent documents to include a description of newly recognized risks
 - Provision of additional information about newly recognized risks to previously enrolled subjects
 - c) Recommend no further action if reported ADR/SAE/SUSAR is not considered serious, unexpected, or relevant to participants.

Step 4. Evaluation of Offsite ADR/SAE/SUSAR Report

1. The SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR, Primary Reviewer and Pharmacologist shall evaluate the submitted list of offsite ADRs/SAEs/SUSARs in terms of risks to the human subject participant within seven (7) working days.
2. The SLMC-IERC Member-in-Charge on ADR/SAE/SUSAR shall report the submitted summary list of the offsite ADRs/SAEs/SUSARs to the SLMC-IERC full board meeting.
3. The SLMC-IERC shall consider the severity, unexpectedness, and potential risks to local participants associated with the reported offsite ADRs/SAEs/SUSARs during full board meeting.
4. During full board board meeting the SLMC-IERC shall recommend the following potential actions:

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- a) Request further information
- b) Consider modifications to local study protocols to address potential risks identified in the offsite reports.
- c) Recommend no further action if reported ADR/SAE/SUSAR is not considered serious, unexpected, or relevant to onsite participants.

Step 5. Notification of SLMC-IERC Action

1. The SLMC-IERC SAE and Noncompliance Coordinator shall prepare the notification to the PI/Project Leader within seven (7) working days regarding the submitted ADR/SAE/SUSAR based on the decisions of the committee:
 - Notice of Action (*SLMC-IERC Template # 03B*) if the decision of the SLMC-IERC is any of the measures mentioned in Step 3.5.
 - Notice of No Action (*SLMC-IERC Template # 04B*) if no further action required.
2. The SLMC-IERC SAE and Noncompliance Coordinator forward the notification to SLMC-IERC Chair for review and signature within five (5) working days via email.
3. The SLMC-IERC SAE and Noncompliance Coordinator forward the notification to the PI/Project Leader upon approval of the chair via email.

Step 6. Documentation

1. The SLMC-IERC SAE and Noncompliance Coordinator shall file the ADR/SAE/SUSAR reports and copies of notifications in the appropriate digital clinical research folder and digital SAE folder within three (3) working days.
2. The SLMC-IERC SAE and Noncompliance Coordinator shall log the ADR/SAE/SUSAR reports in the electronic database for SAEs within three (3) working days.

4.2.5. REFERENCES

Association for the Accreditation of Human Research Protection Programs, Inc. (2018). Evaluation Instrument for Accreditation. Washington, DC: Association for the Accreditation of Human Research Protection Programs, Inc.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (1994). ICH Harmonised Tripartite Guideline Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2a. Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Office of Human Research Protections. (2018). Code of Federal Regulations Title 21, Part 312, Section 312.32. U.S. Department of Health & Human Services.

Philippine Health Research Ethics Board. (2022) National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

World Medical Association. (2024). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory		Revision Effective Date: April 1, 2025
SOP Title: Review of Serious Adverse Events/Suspected Unexpected Serious Adverse Reaction		SLMC-IERC SOP No.: SOP No. 4.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
5	08-2019		5	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 07-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors 1. Addition of Primary Reviewer and Pharmacologist as reviewers 2. Identification of SLMC-IERC Secretariat in charge 3. Removal of SOP on submission ADRs/SAEs/SUSARs to the Medical Group, Pharmacy Therapeutics Committee, and Quality and Patient Safety Group 4. Removal of the clause on expedited reviews of ADR/SAE/SUSAR 5. Addition of NONA template 6. Change in Form no. from 14 to 04E and Template number 08 to 03B 7. Update of references 8. Change of Title from Handling and Monitoring of Safety Reports 9. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Review of Protocol Deviations and Violations Reports	SLMC-IERC SOP No.: SOP No. 4.3

4.3.1. PURPOSE

The purpose of this SOP is to describe the process for handling reports of protocol deviations or violations to the SLMC-IERC and the appropriate actions to be taken by the Committee to minimize risks to human research participants.

4.3.2. SCOPE

This SOP covers the process from receipt of reports of protocol deviation or violation to documentation.

4.3.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Reporting of Protocol Deviation/Violation Report		
1. Define the terms Protocol Deviation, Protocol Violation, Protocol Exception	SLMC-IERC	Every 2 years or as needed
2. Submit Protocol Deviation/Violation Report via email		
a) Protocol violations that pose risks or potential risks to the clinical research participants or others or which can negatively impact the integrity of the data	Principal Investigator/ Project Leader	As soon as possible but no longer than 5 working days upon awareness of the event.
b) Protocol deviations which do not pose any risk to the clinical research participants or others or do not negatively impact the integrity of the data	Principal Investigator/ Project Leader	Before the scheduled SLMC-IERC full board meeting.

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Forward Protocol Deviation/Violation report to SLMC-IERC Member-in-Charge on Protocol Deviation/ Violation	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days
Step 2. Evaluation of the Reports on Protocol Deviations/Violations		
1. Evaluate Protocol Deviation/Violation Report	Assigned SLMC-IERC Primary Reviewer SLMC-IERC Member-in-Charge on Protocol Deviation/Violation	Within 3 working days
a) Recommend immediate course of action if the risks outweigh potential benefits, other participants may be at risk, or the risks have not been appropriately minimized.	SLMC-IERC Member-in-Charge on Protocol Deviation/Violation SLMC-IERC Chair	Within 3 working days
b) Recommend presentation in regular full board meeting if the report is not for immediate action	SLMC-IERC Member-in-Charge on Protocol Deviation/Violation	Within 3 working days
2. Present the deviations/violations report, findings and recommendations	SLMC-IERC Member-in-Charge on Protocol Deviation/Violation	During full board meeting
3. Recommend course of action	Primary Reviewer SLMC-IERC Member-in-Charge on Protocol Deviation/Violation	During full board meeting
4. Decide on the recommended course of action by consensus.	SLMC-IERC	During full board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Notification of SLMC-IERC Action		
1. Prepare notice to PI/Project Leader of the recommended action: a) Notice of Action if the decision of the SLMC-IERC is any of the measures mentioned in Step 2.1.a. b) Notice of No Action if no further action required.	SLMC-IERC SAE and Noncompliance Coordinator	Within 5 working days
2. Forward of Notification to the SLMC-IERC Chair for review and signature via email	SLMC-IERC SAE and Noncompliance Coordinator	Within 5 working days
3. Forward signed Notification to the PI/Project Leader via email	SLMC-IERC SAE and Noncompliance Coordinator	Upon approval of the Chair
Step 4. Documentation		
1. File Protocol Deviation/Violation Report and copies of notifications in the appropriate digital clinical research folder.	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days
2. Log Protocol Deviation/ Violation Reports in the electronic database for Protocol Deviations/ Violations.	SLMC-IERC SAE and Noncompliance Coordinator	Within 3 working days

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4.3.4. PROCEDURES

Step 1. Reporting of Protocol Deviation/Violation Report

1. The following terms shall be defined and use in this SOP:

a) Protocol Deviation:

- a minor or administrative departure from the SLMC-IERC approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior SLMC-IERC approval. It is an accidental or unintentional change to, or non-compliance with the clinical research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the human subject participant's non-adherence, or an unintentional change to or non-compliance with the clinical research protocol on the part of the Principal Investigator/Project Leader or the study team.

Examples of a deviation include:

- A rescheduled study visit
- Failure to collect an ancillary self-report questionnaire
- Subject's refusal to complete scheduled research activities

b) Protocol Violation:

- an accidental or unintentional change to, or non-compliance with the SLMC-IERC approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) not reported or pre-approved by the SLMC-IERC. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.

Examples of protocol violations:

- Failure to obtain valid informed consent or obtaining consent with a faulty document (e.g. non-date stamped form)
- Loss of laptop computer that contained identifiable, private information about subjects (e.g., names, social security numbers, medical information)
- incorrect medication or incorrect dosage
- Not following inclusion/exclusion criteria or enrolling an ineligible participant

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- Falsifying data or research records.
- Failing to follow proper data collection or storage procedures.

c) **Protocol Exception:**

- a temporary protocol deviation that is pre-approved by the sponsor of funding agency. It is generally for a single subject (e.g. the patient/subject is allergic to one of the medications provided as supportive care) or occasionally, a small group of subjects. The protocol exception is usually evaluated by both the sponsor or funding agency and the SLMC-IERC in order to determine that it does not increase the risk to the subject(s), or jeopardize the integrity of the research data. Documentation of the sponsor's pre-approval and SLMC-IERC approval of the exception shall be maintained in the Investigator's research file.
2. Protocol violations/deviations shall be reported by the Principal Investigator/ Project Leader to the SL-IERC using Protocol Deviation/Violation Form (*SLMC-IERC Form # 04F*) via email.
- a) All protocol violations that pose risks or potential risks to the clinical research participants or others or which can negatively impact the integrity of the data should be reported as soon as possible but no longer than five (5) working days after the Principal Investigator/Project Leader becomes aware of the event.
 - b) Protocol deviations which do not pose any risk to the clinical research participants or others or do not negatively impact the integrity of the data have to be reported to the SLMC-IERC before the scheduled SLMC-IERC full board meeting. The report shall include the following:
 - i. Summary of the non-risk related deviations that have occurred since the last SL-IERC review
 - ii. Justification why the Principal Investigator/Project Leader decided these events did not involve increased risks to participants or others or negatively impacted the integrity of the data
 - iii. An explanation whether there is a systemic problem with the approved procedures, processes, data collection methods, etc. that creates the number of deviations that have occurred, and therefore, warrants a revision to the protocol to minimize or eliminate such deviations
3. The SLMC-IERC Secretariat shall forward the report on protocol deviations and/or violations to the SLMC-IERC Primary Reviewer (assigned Reviewer during the initial review



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of the clinical research) and SLMC-IERC Member-in-Charge on Protocol Deviations/Violations or SLMC-IERC Chair via email within three (3) working days.

Step 2. Evaluation of the Reports on Protocol Deviations/Violations

1. The SLMC-IERC Primary Reviewer, Member-in-Charge on Protocol Deviations/Violations, and/or Chair shall evaluate all protocol violations/deviations reported by the Principal Investigator/Project Leader upon receipt of the report.
 - a) If, in the opinion of the SLMC-IERC Primary Reviewer and/or Member-in-Charge on Protocol Deviations/Violations, the risks outweigh potential benefits, other participants may be at risk, or risks have not been appropriately minimized, he/she will notify the SLMC-IERC Chair immediately and recommend and/or request any of the following courses of action during full board meeting:
 - i. Submission of additional information
 - ii. Submission of corrective action plan
 - iii. Invitation to a clarificatory interview
 - iv. Requirement for an amendment
 - v. Conduct of site visit by SLMC-IERC
 - vi. Suspension of recruitment, or
 - vii. Withdrawal of ethical clearance.
 - b) In the absence of any need for immediate action, SLMC-IERC the Member-in-Charge on Protocol Deviations/Violations shall recommend the presentation of the deviations/violations report, findings and recommendations in the next monthly SLMC-IERC full board meeting.
2. The SLMC-IERC the Member-in-Charge on Protocol Deviations/Violations shall present the deviations/violations report, findings and recommendations in the SLMC-IERC full board meeting.
3. During the SLMC-IERC full board meeting, the SLMC-IERC Member-in-Charge on Protocol Deviations/Violations shall have the authority to recommend any one or more of the courses of actions described in Step 2.1.a above.
4. Decision on the course of action shall be made by consensus of the SLMC-IERC members during the full board meeting.

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Step 3. Notification of SLMC-IERC Action

1. The SLMC-IERC SAE and Noncompliance Coordinator shall prepare the notification to the PI/Project Leader regarding the submitted Protocol Deviation/Violation Report based on the decisions of the committee within five (5) working days:
 - o Notice of Action (*SLMC-IERC Template # 03B*) if the decision of the SLMC-IERC is any of the measures mentioned in Step 2.1.
 - o Notice of No Action (*SLMC-IERC Template # 04C*) if no further action required.
2. The SLMC-IERC SAE and Noncompliance Coordinator forward the notification to SLMC-IERC Chair for review and signature within five (5) working days via email.
3. The SLMC-IERC SAE and Noncompliance Coordinator forward the notification to the PI/Project Leader upon approval of the chair via email.

Step 4. Documentation

1. The SLMC-IERC SAE and Noncompliance Coordinator shall file the Protocol Deviation/Violation Report and copies of notifications in the appropriate digital clinical research folder within three (3) working days.
2. The SLMC-IERC SAE and Noncompliance Coordinator shall log the Protocol Deviation/Violation Reports in the database for Protocol Deviations/Violations within three (3) working days.

4.3.5. REFERENCES

Goldfarb, Norman. (2005). Bringing Method to the Madness: Protocol Deviation and Violation Codes. Journal of Clinical Research Best Practices. Vol.1 (11).

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Maine Medical Center Research Institute. (2018). MMC HRPP Standard Operating Procedures. Maine: Maine Medical Center Research Institute.

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Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 12-2024		6	1. Compliance with suggestions of FERCAP/PHREB surveyors 2. Identification of SLMC-IERC Secretariat in charge 3. Correction of Workflow showing all PD/PVs are reviewed in Full Board 4. Deletion of statement in Step 1.2 "However, when five (5) or more deviations of the same nature occurs, these must be reported to the SL-IERC after the 5th deviation". Step 2 was streamlined. 5. Addition of Template No. 04C 6. Change in Form no. from 15 to 04f and Template number 08 to 03B 7. Update of references 8. Change of Title from Reporting and Handling of Protocol Deviations and Violations 9. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Review of Protocol Amendments	SLMC-IERC SOP No.: SOP No. 4.4

4.4.1. PURPOSE

The purpose of this SOP is to describe the process for handling amendments to study protocols to ensure regulatory and ICH-GCP compliance. This encompasses changes or modifications in SLMC-IERC approved protocol, Informed Consent form, Investigator's Brochure, addition of new investigators/proponents, study team and/or sites.

4.4.2. SCOPE

This SOP covers the process from receipt of request for amendment and amended clinical research protocol documents to documentation.

4.4.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receipt of Protocol Amendment Documents		
1. Submit soft copies of the protocol amendment documents via email	Principal Investigator/ Project Leader	As needed
2. Receive and check for accuracy and completeness of protocol amendment documents of Letter of Request, Protocol Amendment Form, Amended Protocol/ICF, and Summary of Changes	SLMC-IERC Amendments Coordinator	Within 3 working days
3. Forward submitted protocol amendment documents to SLMC-IERC Member-in-Charge of Protocol Amendments and to SLMC-IERC Primary Reviewer	SLMC-IERC Amendments Coordinator	Within 2 working days of receipt of complete documents

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 2. Evaluation of the Protocol Amendment Documents		
1. Review protocol amendments or changes	SLMC-IERC Primary Reviewer SLMC-IERC Member-in-Charge of Protocol Amendments	Within 14 calendar days
2. Confirm PI/Project Leader's classification of the amendment as a "Major" or "Minor" modification	SLMC-IERC Primary Reviewer	Within 14 calendar days
3. Submit accomplished Protocol Amendment Form to the SLMC-IERC Member-in-Charge of Protocol Amendments	SLMC-IERC Primary Reviewer	Within 14 calendar days
4. Classify type of review based on the classification of the amendments: Full Board or Expedited	SLMC-IERC Member-in-Charge of Protocol Amendments	Within 7 calendar days
5. If for full board review, present amendments, findings and recommendations to the SLMC-IERC	SLMC-IERC Member-in-Charge of Protocol Amendments	During Full Board meeting
6. Discuss findings and vote on the recommended course of action during Full Board meeting	SLMC-IERC	During Full Board meeting
7. If expedited review, recommend appropriate course of action	SLMC-IERC Primary Reviewer SLMC-IERC Member-in-Charge of Protocol Amendments	Within 30 calendar days upon receipt of the protocol amendments.
8. Collect accomplished protocol amendment evaluation forms from the SLMC-IERC Member-in-Charge of Protocol Amendments and from the Primary Reviewer	SLMC-IERC Amendments Coordinator	Within 3 working days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Preparation of Notice of Action or Approval		
1. Prepare Notice of Action or Approval	SLMC-IERC Amendments Coordinator	Within 5 working days
2. Send Notice of Action or Approval for review and signature of SLMC IERC Chair via email	SLMC-IERC Amendments Coordinator	Within 2 working days
3. Issue Notice of Action or Approval to the Principal Investigator/Project Leader via email	SLMC-IERC Amendments Coordinator	Within 3 working days
4. Respond to the requests/recommendation of the SLMC-IERC	Principal Investigator/Project Leader	Within 30 calendar days
Step 4. Documentation		
1. Store all correspondences and reports related to protocol amendments in the SLMC-IERC digital file folder.	SLMC-IERC Amendments Coordinator	Within 3 working days
2. Update the SLMC-IERC electronic Protocol Database and electronic Protocol Amendments Database	SLMC-IERC Amendments Coordinator	Within 3 working days

4.4.4. PROCEDURES

Step 1. Receipt of Protocol Amendment Documents

1. Principal Investigator/Project Leader shall submit the soft copies of the following via email:
 - Letter of Request
 - Filled-up Protocol Amendment Form (SLMC-IERC Form # 04G)
 - Amended protocol (one with track changes and one clean copy) or
 - Amended Informed Consent Form (one with track changes and one clean copy)

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- Summary of protocol/ICF changes
- Names of new investigators/proponents or study team member, if applicable
- Name of new site, if applicable
- 2. The SLMC-IERC Amendments Coordinator shall receive and review the submitted documents for accuracy and completeness within three (3) working days, including:
 - Version numbers align with those in the summary of changes and Principal Investigator/Project Leader's letter
 - Added/new text is shown in bold letters
 - Deleted text is shown with strikethrough
- 3. The SLMC-IERC Amendments Coordinator shall forward the submitted amended protocol/ICF documents and Protocol Amendment Form to the SLMC-IERC Primary Reviewer who did initial review of the protocol and to Member-in-Charge of Protocol Amendments via email within two (2) working days of receipt of complete documents

Step 2. Evaluation of the Protocol Amendment Documents

1. The SLMC-IERC Primary Reviewer and Member-in-Charge of Protocol Amendments shall review the amendments or changes in the protocol/ICF.
2. The SLMC-IERC Primary Reviewer shall confirm the PI/Project Leader's classification of the amendment as a "Major" or "Minor" modification, based on the following:
 - a) **Major Modification** – any change to a previously approved protocol that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of major amendments (modifications/changes) to a protocol may include but not limited to:
 - i. Addition of a new subject population (e.g. control group, additional cohort, etc.), changes in number of subjects or age range of subjects;
 - ii. Addition of research procedures that involve greater than minimal risk to subjects (e.g. addition of new drug to a treatment regimen, addition of invasive procedures, change in route or frequency of drug administration, change of comparator drug, duration of exposure to the drug, etc.);
 - iii. Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
 - iv. Addition of blood/tissue/cell banking or genetic testing;

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- v. Deletion of follow-up visits that appear necessary for monitoring subject safety and welfare;
- vi. Broadening the range of the inclusion criteria;
- vii. Narrowing the range of the exclusion criteria;
- viii. Appointment of new Principal Investigator/Project Leader or new investigators/proponents;
- ix. Changes in the investigational drug (e.g. addition of stability data/change of expiry date, change of formulation, additional toxicology data, change to route of synthesis);
- x. Addition of new significant risks or serious unexpected adverse events to the informed consent document;
- xi. Changes which, in the opinion of the SLMC-IERC Reviewer and Member-in-Charge, do not meet the criteria or intent of a minor modification.

b) Minor Modification – any change to previously approved protocol, i.e. changes in clinical trial/research related activities that does not materially affect the assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Examples of minor amendments (modifications/changes) include, but are not limited to:

- i. Minor increases or decreases in the number of participants;
- ii. Changes in remuneration;
- iii. Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statements;
- iv. Narrowing the range of inclusion criteria;
- v. Broadening the range of exclusion criteria;
- vi. Alterations in the dosage form (e.g. tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant);
- vii. Decreasing the number or volume of biological sample collections, provided that such change does not affect the collection of information related to safety evaluations;
- viii. An increase in the length of confinement or number of study visits for the purposes of increased safety monitoring;
- ix. A decrease in the length of confinement or study visits, provided that such a decrease does not affect the collection of information related to safety evaluations.

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3. The SLMC-IERC Primary Reviewer shall submit its accomplished Protocol Amendment Form to the SLMC-IERC Member-in-Charge of Protocol Amendments.
4. The SLMC-IERC Member-in-Charge of Protocol Amendments shall classify the type of review based on the classification of the amendments.
 - a) Full board review of the protocol amendment shall be done if:
 - With major protocol amendment
 - If previously approved full board
 - Requested by the Principal Investigator/Project Leader
 - SLMC-IERC Member-in-Charge of Protocol Amendments decides that it should be presented to SLMC-IERC Members
 - b) Expedited review of the protocol amendment shall be conducted if:
 - The amendments are minor and do not significantly affect the risk-benefit assessment or the study design.
 - The protocol was initially reviewed and approved via the expedited process.
5. If for full board review, the SLMC-IERC Member-in-Charge of Protocol Amendments shall present to the full board SLMC-IERC his/her and Primary Reviewers' findings and recommendations on the protocol amendments.
6. The SLMC-IERC shall discuss the protocol amendment and vote on recommended course of action as follows:
 - a) Approve
 - b) Request further information if additional details are needed
 - c) Suggest modifications to the amendment to address specific concerns or requirements.
 - d) For acknowledgment
7. If for expedited review, the SLMC-IERC Member-in-Charge of Protocol Amendments and Primary Reviewer shall recommend the course of action as described in Step 2.7 above within 30 calendar days upon receipt of the protocol amendments.
8. The SLMC-IERC Amendments Coordinator shall collect the accomplished protocol amendment evaluation forms from the SLMC-IERC Member-in-Charge of Protocol Amendments and from the Primary Reviewer within three (3) working days.

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Step 3. Preparation of Notice of Action or Approval

1. The SLMC-IERC Amendments Coordinator shall prepare a Notice of Approval (*SLMC-IERC Template # 04D*) if the protocol amendment is approved. Otherwise, a Notice of Action (*SLMC-IERC Template # 03B*) shall be prepared within five (5) working days. (See SOP 3.5).
2. The SLMC-IERC Amendments Coordinator shall send the Notice of Action or Notice of Approval to the SLMC-IERC Chair for review and signature via email within two (2) working days.
3. The SLMC-IERC Amendments Coordinator shall send the Notice of Action or Notice of Approval and *SLMC-IERC Composition (SLMC-IERC Template # 03D)* to the Principal Investigator/Project Leader within three (3) working days.
4. The Principal Investigator/Project Leader shall respond to the requests/recommendation of the SLMC-IERC within 30 calendar days.

Step 4. Documentation

1. The SLMC-IERC Amendments Coordinator shall store all correspondences and reports related to protocol amendments in the SLMC-IERC digital file folder within three (3) working days.
2. The SLMC-IERC Amendments Coordinator shall update the SLMC-IERC electronic Protocol Database and electronic Protocol Amendments Database within three (3) working days.

4.4.5. REFERENCES

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Directive 2001/20/EC of the European Parliament and of the Council

Office of Human Research Protections. (2018). Code of Federal Regulations Title 21, Part 312, Section 312.30. U.S. Department of Health & Human Services.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—*Nothing Follows*—

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Identification of SLMC-IERC Secretariat responsible 2. Change in Form No. from 07 to 04G 3. Change in Template No. from 08 to 03B; 09 to 04D 4. Inserted course of action 5. Inserted documentation section 6. Updated References 7. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Site Monitoring Visit	SLMC-IERC SOP No.: SOP No. 4.5

1.5.1. PURPOSE

The purpose of this SOP is to describe the process of when and how a study site, internal (SLMC QC and GC) or off-sites shall be visited and monitored for its performance or compliance to ICH-GCP guidelines.

1.5.2. SCOPE

This SOP covers the process for identifying clinical research studies for monitoring, conducting site monitoring visits, and evaluating the findings from these visits.

1.5.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Routine Monitoring of Study Site		
1. Conduct routine monitoring of clinical studies (sponsor- or investigator-initiated): a) All moderate to high-risk interventional studies; 10% of minimal-risk non-interventional studies (randomly) b) Monitor study site based on Ethical Clearance anniversary	SLMC-IERC Member and/or CHRP Clinical Research Monitor (CRM)	At least once a year
Step 2. "For-Cause Monitoring" of Study Site		
2. Initiate "for-cause" monitoring based on specific issues	SLMC-IERC Member, Chair, or Committee	As needed

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 3. Monitoring Visit Activities (scheduled or “for-cause”)		
1. Before the study site monitoring visit		
i. Request protocol files for monitoring from SLMC-IERC Initial Submissions Coordinator	Representative SLMC-IERC Member Clinical Research Monitor	At least 14 calendars days before the visit
ii. Share soft copies of protocol files and other documents to the SLMC-IERC Representative(s) or Clinical Research Monitor(s)	SLMC-IERC Initial Submissions Coordinator	At least 14 calendars days before the visit
iii. Notify Principal Investigator/ Project Leader of the scheduled study site monitoring visit via email	Representative SLMC-IERC Member Clinical Research Monitor	At least 14 calendars days before the visit
2. During the study site monitoring visit		
i. Monitor site using Clinical Research/ Site Monitoring Form (CRMF)	Representative SLMC-IERC Member and/or Clinical Research Monitor	During visit
ii. Discuss with Principal Investigator/ Project Leader or Coordinator of the findings	Representative SLMC-IERC Member Clinical Research Monitor	During visit
iii. Calculate overall performance of the PI/Project Leader in the conduct of the research	Representative SLMC-IERC Member Clinical Research Monitor	During visit

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
iv. Sign the accomplished CRMF and provide copy to Principal Investigator/Project Leader	Representative SLMC-IERC Member Clinical Research Monitor Principal Investigator/Project Leader	During visit
3. After the study site monitoring visit		
i. Submit accomplished CRMF to SLMC-IERC Member-in-charge of Protocol Violations/Deviation	Representative SLMC-IERC Member and/or Clinical Research Monitor	Within 7 working days
ii. Review findings of the study site monitoring visit	SLMC-IERC Member-in-charge of Protocol Violations/Deviation	Within 7 working days
Step 4. Evaluation of the site monitoring visit findings		
1. Recommend Full board review if findings have significant impact on the safety of study participants	SLMC-IERC Member-in-charge of Protocol Violations/Deviation	Within 14 calendar days
i. Present findings in SLMC-IERC full board meeting if findings have significant impact on the safety of study participants	SLMC-IERC Member-in-charge of Protocol Violations/Deviation	During full board meeting
ii. Discuss findings and recommended course of action	SLMC-IERC	During full board meeting
iii. Decide by voting on recommended appropriate action	SLMC-IERC	During full board meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. If issues of the study site monitoring visit involve minimal or no risk to the study participants, submit the accomplished CRMF with recommendations to the SL-IERC Chair.	SLMC-IERC Member-in-charge of Protocol Violations/Deviation	Within 14 calendar days
Step 5. Preparation of Notice of Action or Notice of No Action		
4. Prepare Notice of Action (if there are queries) or Notice of No Action (if no issues) and send signed document (by SLMC-IERC Chair) to the concerned Principal Investigator/ Project Leader	SLMC-IERC SAE and Compliance Coordinator	Within 14 calendar days
Step 6. Documentation		
1. Store accomplished and signed CRMF and a copy of all correspondences in the SLMC-IERC digital file folder.	SLMC-IERC SAE and Compliance Coordinator	Within 3 working days
2. Update SLMC-IERC Protocol Database and Protocol Violation/ Deviation Database	SLMC-IERC SAE and Compliance Coordinator	Within 3 working days

4.5.4. PROCEDURES

Step 1. Routine Monitoring of Study Site

1. Routine monitoring of conduct of clinical studies, whether Sponsor-initiated or Investigator-initiated, shall be conducted by the designated SLMC-IERC Member and/or Center for Human Research Protection (CHRP) Clinical Research Monitor (CRM).
 - a) Study sites or Principal Investigators/Project Leaders of interventional clinical research studies (moderate to high risk) and ten percent (10%) of randomly selected non-interventional clinical research studies (minimal risk) in St. Luke's Medical Center Quezon City and Global shall be visited and monitored at least once a year.



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- b) Monitoring of a study site shall be based on the anniversary of the Ethical Clearance. However, Progress Report shall be submitted by the Principal Investigator/Project Leader based on the risks as stated in the Ethical Clearance (see SOP No. 4.1 Step 1.2):
- Low/Minimal Risk – Annually from the date of issuance of initial Ethical Clearance
 - Moderate/Medium Risk – Annually from the date of issuance of initial Ethical Clearance
 - High risk – Semi-annually or more frequently, based on specific conditions such as enrollment milestones or significant protocol changes and continuing review annually.

Step 2. “For-Cause Monitoring” of Study Site

1. “For-cause monitoring” shall be done at any site upon recommendation of any SLMC-IERC Member, SLMC-IERC Chair, or SLMC-IERC. “For-cause monitoring” shall be based on the following reasons/criteria:
 - New study site(s)
 - High number of protocol violations or deviations
 - Large number of studies carried out at the study site or by the Principal Investigator/Project Leader
 - Reports of remarkable serious adverse events (SAE)/suspected unexpected serious adverse reaction (SUSAR)
 - High recruitment rate
 - Complaints received from clinical research participants or any other person
 - Non-compliance or failure to submit required documents i.e. progress reports/annual reports
 - Any other cause as decided by the SLMC-IERC

Step 3. Monitoring Visit Activities (scheduled or “for-cause”)

1. Before the study site monitoring visit
 - i. The SLMC-IERC Representative(s) and/or CRM(s) shall coordinate with the SLMC-IERC Initial Submissions Coordinator for the protocol files of clinical research studies that will be monitored, either for routine or “for-cause” monitoring.

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- ii. The SLMC-IERC Initial Submissions Coordinator shall share the soft copies of the protocol files and other documents pertinent to the clinical research to be monitored to the SLMC-IERC Representative(s) or CRM(s). The SLMC-IERC Representative(s) or Clinical Research Monitor(s) may photocopy some parts of the files for comparison with the study site files.
- iii. The SLMC-IERC Representative(s) and/or CRM(s) shall notify the study site Principal Investigator/Project Leader using the "Clinical Research/Site Monitoring Notice Form" about the scheduled site visit (*SLMC-IERC Template # 04E*) via email.

2. During the study site monitoring visit

1. The SLMC-IERC Representative(s) and/or CRM(s) shall check the compliance of the Study Team on the following using the Clinical Research/Site Monitoring Form (*SLMC-IERC Form # 04H*):
 1. The following source documents/investigational files are filed properly:
 - Approved protocol
 - Revised protocol approved by the IERC
 - Approved Informed Consent Form (ICF)
 - Revised ICF approved by the IERC
 - Investigational Brochure
 - Ethical Clearance
 - Clinical Trial Agreement
 - Other communication letters with IERC and Sponsor
 - Approved flyer or advertisement materials
 2. All the study files are filed in a locked cabinet
 3. All informed consent/assent forms (latest IERC approved version) are properly signed and dated by the patient/LAR, Principal Investigator/Project Leader, and/or witness (*SLMC-IERC Form # 04I*)
 4. All enrolled subjects have hard copies of the signed ICFs
 5. Persons who obtained the ICFs are all stated in the Delegation Log
 6. All eligibility criteria are met
 7. No subject is enrolled pending SLMC-IERC approval of the revised ICF
 8. All subjects are asked to re-consent using the revised SLMC-IERC approved ICF, when necessary
 9. All Case Report Forms (CRF) are accomplished within two (2) weeks of the subjects' visit (Check CRFs of 10% of enrolled subjects)

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10. Data in CRFs are valid when checked against the source documents (for primary and secondary outcomes)
 11. All protocol deviations/violations are reported to the SLMC-IERC.
 12. All ADRs, SAEs and SUSARs are reported to the IERC within 24 hours to 7 days upon discovery
 13. All progress reports are submitted to the SLMC-IERC on time.
 14. Ethical Clearance is renewed one year from date of issuance
 15. Terminal report is submitted to the SLMC-IERC.
 16. Final report is submitted to the SLMC-IERC.
 17. All GCP certificates of the study team are up-to-date
 18. All CVs of the study team are filed properly
 19. All members of the study team are included in the Delegation of Responsibility
 20. All members of the study team are trained before the start of the study
 2. The SLMC-IERC Representative(s) and/or CRM(s) shall discuss with the Principal Investigator/Project Leader the issue(s) that need to be addressed immediately after the monitoring visit.
 3. The SLMC-IERC Representative(s) and/or CRM(s) shall calculate the overall performance of the PI/Project Leader in the conduct of the research. Overall performance shall be calculated as total compliance score divided by the number of applicable items x 2 x 100%.
 4. The SLMC-IERC Representative(s) and/or CRM(s) and the Principal Investigator/Project Leader shall sign the CRMF. A copy of the signed CRMF shall be provided to the Principal Investigator/Project Leader.
- 3. After the study site monitoring visit**
1. The SLMC-IERC Representative(s) and/or CRM(s) shall submit the accomplished CRMF to the SLMC-IERC Member-in-charge of Protocol Violations/Deviation after the monitoring visit.
 2. The SLMC-IERC Member-in-charge of Protocol Violations/Deviation shall review the accomplished CRMF.



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Step 4. Evaluation of the site monitoring visit findings

1. If the SLMC-IERC Member-in-charge of Protocol Violations/Deviation judges that the issues of the study site monitoring visit have significant impact on the safety of study participants, he/she may recommend full board review of the findings.
 - i. The SLMC-IERC Member-in-charge of Protocol Violations/Deviation shall present the findings to the Committee.
 - ii. The SLMC-IERC Members shall discuss the findings of the monitoring visit and take appropriate specific action by voting for any of the following:
 - Restrictions on enrollment
 - Recommendations for additional training
 - Recruiting additional members in the study team
 - Revising/providing qualifications/experience criteria for members of the study team
 - Suspension/termination of the study
2. If the SLMC-IERC Member-in-charge of Protocol Violations/Deviation judges that the issues of the study site monitoring visit involve minimal or no risk to the study participants, he/she shall submit the accomplished CRMF with his/her recommendations and signature to the SL-IERC Chair.

Step 5. Preparation of Notice of Action

1. The SLMC-IERC SAE and Compliance Coordinator shall prepare and send a Notice of Action (if there are queries) or Notice of No Action (if no issues) signed by the SL-IERC Chair to the concerned Principal Investigator/Project Leader.

Step 6. Documentation

1. The SLMC-IERC SAE and Compliance Coordinator shall keep the accomplished and signed CRMF and a copy of all correspondences in the SLMC-IERC digital file folder.
2. The SLMC-IERC SAE and Compliance Coordinator shall update the SLMC-IERC Protocol Database and Protocol Violation/Deviation Database.

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4.5.5. REFERENCES

Forum for Ethics Review Committees in India. (2014). FERCI MODEL SOP 16/V1: Site Monitoring and Post-Monitoring Activities. Mumbai: Forum for Ethics Review Committees in India.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Karlberg JPE and Tam SYM. (2011). Study Site SOP Standardization - 4S - Project. Hong Kong: Clinical Trials Centre. The University of Hong Kong, Li Ka Shing Faculty of Medicine.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
0	07-2018		0	New SOP	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
1	08-2019		1	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
2	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
3	03-2024 12-2024		2	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Simplified the Scope statement 2. Removal of CHRP Head in the monitoring and reporting. 3. Change of responsible person from SLMC-IERC Member Secretary to Member-in-Charge of Protocol Violations/ Deviations 4. Identification of SLMC-IERC Secretariat in charge 5. Change in Form No. from 18 to 04G; from 19 to 04H 6. Change in Template No. from 16 to 04E 7. Added section on documentation 8. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: DOCUMENTATION AND ARCHIVING	SLMC-IERC SOP No.: SOP No. 5

5. STATEMENT ON DOCUMENTATION AND ARCHIVING

The St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC) is committed to the meticulous maintenance of its documentation and archiving system. By methodically managing all pertinent records, from meeting agendas to communication logs, this SOP upholds the most stringent regulatory standards and best practices for record-keeping. The policy emphasizes the utmost importance of the integrity and confidentiality of records and reinforces the transparency and accountability of the SLMC-IERC's activities.

SOP 5 outlines the following procedures:

- SOP 5.1 Preparation of Notice of Meeting and Agenda
- SOP 5.2 Preparation and Distribution of Minutes of Meetings
- SOP 5.3 Management of Communications
- SOP 5.4. Management of Administrative and Clinical Research Protocol Files
- SOP 5.5 Management of Databases

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SOP Title: Preparation of Notice of Meeting and Agenda	SLMC-IERC SOP No.: SOP No. 5.1

5.1.1. PURPOSE

The purpose of this SOP is to describe the procedures for the preparation of the Agenda and Notice of a regular SLMC-IERC meeting.

5.1.2. SCOPE

This SOP covers the procedures from preparation of the Meeting Agenda to filing of Agenda in the digital file folder.

5.1.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Setting of Meeting Agenda		
1. Prepare Tentative Agenda (Template #05A)	SLMC-IERC Initial Submissions Coordinator SLMC-IERC Chair	At least 2 weeks before meeting
Step 2. Scheduling of SLMC-IERC Meetings		
1. Schedule the date of the SLMC-IERC Meeting on the third Wednesday of the month, or as decided by the committee and determine if the meeting will be virtual, hybrid, or face-to-face.	SLMC-IERC Chair	During Full Board meeting
Step 3. Notification of SLMC-IERC Members and Notification of Presenters		
1. Email meeting schedule (date, time, link/venue) to members	SLMC-IERC Initial Submissions Coordinator	At least 2 weeks before meeting

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. Email invitations to Subject Matter Experts or External/Independent Consultants	SLMC-IERC Initial Submissions Coordinator	At least 2 weeks before meeting
3. Send Tentative Agenda and Minutes of previous meeting via email.	SLMC-IERC Initial Submissions Coordinator	At least 2 days before meeting
Step 4. Venue and Logistical Preparation		
1. Reserve R&B Conference Room (if applicable)	SLMC-IERC Initial Submissions Coordinator	At least 2 weeks before meeting
2. Submit Request Forms to: - Food and Nutrition Department for food - Transport Services for transportation (if needed)	SLMC-IERC Initial Submissions Coordinator	At least 1 week before meeting
Step 5. Documentation		
1. Maintain records of the finalized Agenda and essential documents in the digital file folder for Minutes of Meeting and Agenda.	SLMC-IERC Initial Submissions Coordinator	Within 2 working days

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5.1.4. PROCEDURES

Step 1. Setting of Meeting Agenda

1. The SLMC-IERC Initial Submissions Coordinator, in consultation with the SLMC-IERC Chair, shall prepare the Tentative Agenda (*SLMC-IERC Template #05A Agenda*) for the regular meeting of the SLMC-IERC. The standard Agenda for a regular SLMC-IERC meeting shall include the following:
 - a) Call to Order
 - b) Invocation
 - c) Determination of quorum and presence of non-institutional members
 - d) Disclosure of Conflict of Interest
 - e) Approval of the Agenda
 - f) Reading and Approval of Minutes of the previous meeting
 - g) Matters arising from Minutes of the previous meeting
 - h) For full board review
 - i. Sponsor-initiated Clinical Trials
 - ii. Investigator-initiated Clinical Research studies
 - iii. Response to Notice of Action
 - iv. Reports of SLMC-IERC Members-in-Charge of:
 - o Protocol Amendments
 - o Continuing Review/Progress Report/Final Report
 - o Protocol Deviations/Violations
 - o SAEs
 - o Study Site Monitoring Visit
 - v. Matters for Information and Acknowledgement
 - o Updates on protocols reviewed
 - Full board review
 - Sponsor-initiated
 - Response to Notice of Action
 - Expedited review
 - Exempt from Review
 - o Protocol Amendments
 - o Response to Notice of Action



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
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- Study updates
 - Study Withdrawals/Study Close Out/Study Termination
 - Protocol Deviation/Violation
 - Continuing Review
- Safety reports
- Materials for information and acknowledgement
- i) Announcements
- j) Other matters
- k) Schedule of next meeting
- l) Adjournment

Step 2. Scheduling of SLMC-IERC Meetings

1. The regular meetings of the SLMC-IERC Members shall be held on the third Wednesday of each month, or as scheduled by the committee, and may be held virtually, hybrid, or face-to-face.

Step 3. Notification of SLMC-IERC Members and Notification of Presenters

1. The SLMC-IERC Initial Submissions Coordinator shall send the meeting schedule (including date, time, and link for virtual meetings or venue for face-to-face meetings) to all Members of the SLMC-IERC two (2) weeks prior to the scheduled meeting via email.
2. The SLMC-IERC Initial Submissions Coordinator shall send an invitation to the Subject Matter Expert or External/Independent Consultant to be present during the full-board meeting two (2) weeks before the scheduled full board meeting.
3. The SLMC-IERC Secretariat shall send the Tentative Agenda of the next meeting and Minutes of the previous meeting via email two (2) days before the meeting.

Step 4. Venue and Logistical Preparation

1. The SLMC-IERC Initial Submissions Coordinator shall reserve the use of the R&B Conference Room for the SLMC-IERC meeting.
2. The SLMC-IERC Initial Submissions Coordinator shall prepare the following requests:
 - Dietary Request Form to Food and Nutrition Department
 - Transport Request Form to Transport Services Department, if needed

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Step 5. Documentation

1. The SLMC-IERC Initial Submissions Coordinator shall maintain records of the finalized Tentative Agenda and essential documents in the digital file folder for Minutes of Meeting and Agenda.

5.1.5. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

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SOP Title: Preparation of Notice of Meeting and Agenda		SLMC-IERC SOP No.: SOP No. 5.1

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓			SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Change in Template No. from 12 to 05A 2. Notice of meeting via email 3. Identification of SLMC-IERC Secretariat in charge 4. Added documentation section 5. Updated References 6. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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SOP Title: Preparation of Distribution of Minutes of Meeting	SLMC-IERC SOP No.: SOP No. 5.2

5.2.1. PURPOSE

The purpose of this SOP is to describe the procedures for the preparation of the draft of the Minutes of the SLMC-IERC Meeting and its final approval.

5.2.2. SCOPE

This SOP covers the process from real-time recording of the Minutes up to the approval and distribution of the Minutes to the SLMC-IERC Members.

5.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Recording of Minutes of Meeting		
1. Take real-time Minutes	SLMC-IERC Member-Secretary SLMC-IERC Secretariat Coordinators	During meeting
2. Record Meeting using Google Meet's recording feature	SLMC-IERC Initial Submissions Coordinator	During meeting
3. Upload Google Meet recording in SLMC-IERC Google Drive and server under the Minutes of Meeting and Agenda	SLMC-IERC Initial Submissions Coordinator	Immediately after the meeting
Step 2. Preparation of draft copy of the Minutes (SLMC-IERC Template # 05B Minutes of Meeting)		
1. Prepare the draft of the Minutes based on recording and real-time notes	SLMC-IERC Secretariat Coordinators	Within 14 calendar days

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. Send draft of the Minutes to the SLMC-IERC Member-Secretary for revisions/corrections	SLMC-IERC Initial Submissions Coordinator	Within 14 calendar days
3. Revise/correct the draft Minutes	SLMC-IERC Member-Secretary	Within 7 calendar days
4. Distribute the draft Minutes via email to the SLMC-IERC Members	SLMC-IERC Initial Submissions Coordinator	At least 2 days before the regular meeting
Step 3. Documentation		
1. Update and finalize the Minutes once approved during the next meeting	SLMC-IERC Initial Submissions Coordinator	Within 2 working days after the meeting
2. Store approved Minutes in a digital folder for Minutes of Meeting and Agenda	SLMC-IERC Initial Submissions Coordinator	Within 2 working days after the meeting

5.2.4. PROCEDURES

Step 1. Recording of Minutes of Meeting

1. The SLMC-IERC Member-Secretary and Secretariat Coordinators shall simultaneously take minutes in real-time during the SLMC-IERC meeting.
2. The meeting shall be recorded using Google Meet's recording feature, ensuring that all discussions are captured accurately.
3. The SLMC-IERC Initial Submissions Coordinator shall upload the Google Meet recording to the SLMC-IERC Google Drive and server immediately after the meeting under the Minutes of Meeting and Agenda digital folder. The recording file shall be labeled with the meeting date (year, month, day) for easy retrieval.

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Step 2. Preparation of draft copy of the Minutes (SLMC-IERC Template # 05B Minutes of Meeting)

1. The SLMC-IERC Secretariat Coordinators shall prepare the draft of the Minutes based on recording and real-time notes using the following format:
 - Date and venue of the meeting
 - Attendance/Absences
 - Call to order by person presiding
 - Invocation
 - Declaration of quorum and presence of non-institutional members
 - Approval of the Agenda
 - Disclosure of Conflict of interest
 - Reading and approval of the Minutes of the previous meeting
 - Time when the meeting started
 - Items discussed in the approved agenda
 - Decision on matters discussed i.e. approval/disapproval of clinical research studies
 - Schedule of the next SLMC-IERC Meeting
2. The SLMC-IERC Initial Submissions Coordinator shall send the draft of the Minutes of Meeting to the SLMC-IERC Member Secretary for revisions/corrections.
3. The SLMC-IERC Member-Secretary shall make corrections in the draft of the Minutes of Meeting.
4. The SLMC-IERC Initial Submissions Coordinator shall send the corrected Minutes to the SLMC-IERC members via email two (2) days before the regular meeting.

Step 3. Documentation

1. Once the Minutes are approved during the subsequent meeting, the SLMC-IERC Initial Submissions Coordinator shall update the Minutes document to reflect the final version.
2. The SLMC-IERC Initial Submissions Coordinator shall store the approved Minutes in a digital folder for Minutes of Meeting and Agenda

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SOP Title: Preparation of Distribution of Minutes of Meeting	SLMC-IERC SOP No.: SOP No. 5.2

5.2.5. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

--NOTHING FOLLOWS--

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLMC-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	September 2019
6	06-2022	✓	6	Saving of Minutes Mp3 recording to cloud instead of CD	SLMC-IERC Members	Prospero Ma. Tuaño, MD SLMC-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE		Document Type: MANUAL
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SOP Title: Preparation of Distribution of Minutes of Meeting		SLMC-IERC SOP No.: SOP No. 5.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 12-2024		7	Compliance with suggestions of FERCAP/PHREB surveyors Changes: 1. Added simultaneous real-time Minutes taking by SLMC-IERC Member Secretary and Secretariat Coordinators 2. Inserted storage of recording in Google cloud and server 3. Change in Template No. from 13 to 05B 4. Identification of SLMC-IERC Secretariat in charge 5. Added documentation section 6. Updated References 7. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Preparation of Distribution of Minutes of Meeting	SLMC-IERC SOP No.: SOP No. 5.2

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Communications	SLMC-IERC SOP No.: SOP No. 5.3

5.3.1. PURPOSE

The purpose of this SOP is to describe the process of managing SLMC-IERC email communications that will ensure proper logging, distribution and documentation of all communications to and from the SLMC-IERC.

5.3.2. SCOPE

This SOP covers the process from the receipt of email communications to their logging in the Email Communications Tracker and distribution to relevant recipients.

5.3.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Checking of emails by SLMC-IERC Submissions Processor		
1. Regularly check Gmail emails	SLMC-IERC Submissions Processor	Daily
2. Label each email appropriately based on content and relevance and using Gmail's labeling and color-coding feature to identify responsible SLMC-IERC Secretariat Coordinator	SLMC-IERC Submissions Processor	Upon receipt of email
3. Log email details in the Email Communications Tracker database	SLMC-IERC Submissions Processor	Upon receipt of email
Step 2. Checking of emails by SLMC-IERC Secretariat Coordinators		
1. Regularly review Email Communications Tracker database and assigned emails	SLMC-IERC Secretariat Coordinators	Daily
2. Address all assigned emails	SLMC-IERC Secretariat Coordinators	Within 3 working days

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SOP Title: Management of Communications	SLMC-IERC SOP No.: SOP No. 5.3

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Update Email Communications Tracker database to reflect the status once emails have been addressed.	SLMC-IERC Secretariat Coordinators	Immediately after email is addressed

5.3.4. PROCEDURES

Step 1. The SLMC-IERC Submissions Processor shall:

1. Check all incoming Gmail emails regularly.
2. Label each email appropriately based on its content and relevance. Labels should include the SLMC-IERC Secretariat Coordinator responsible for the email and should utilize Gmail's color-coding feature to highlight emails according to the coordinator in charge.
3. Log the emails chronologically in the Email Communications Tracker database. The Tracker shall have the following fields:
 - Date of encoding or logging
 - New or response from PI/Project leader
 - Date of email
 - Protocol-related or non-protocol-related
 - EC Reference Number, if applicable
 - Name of sender
 - Email recipient
 - Email subject
 - Email content/summary
 - SLMC-IERC Secretariat Coordinator responsible
 - Date of email response
 - Remarks

Step 2. The SLMC-IERC Secretariat Coordinators shall:

1. Regularly check the emails and Email Communications Tracker database
2. Address all emails assigned to them

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SOP Title: Management of Communications	SLMC-IERC SOP No.: SOP No. 5.3

- Update the Email Communications Tracker database to reflect the status once emails have been addressed.

5.3.5. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022		6	Saving of Minutes Mp3 recording to cloud instead of CD	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE		Document Type: MANUAL
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SOP Title: Management of Communications		SLMC-IERC SOP No.: SOP No. 5.3

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
7	03-2024 12-2024		7	Compliance with suggestions of FERCAP/PHREB surveyors 1. Revised procedures for checking, labeling, and logging emails to be more specific about the process, including fields in the Email Communications Tracker. 2. Logbook replaced with digital databases for managing communications. 3. Updated to reflect the use of Gmail's features for email labeling and color-coding. 4. Change in SOP No. from 5.4 to 5.3. 5. Update of reference 6. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Administrative and Clinical Research Protocol Files	SLMC-IERC SOP No.: SOP No. 5.4

5.4.1. PURPOSE

The purpose of this SOP is to outline procedures for the management of all administrative and clinical research protocol files within the SLMC-IERC, including the receipt, sorting, maintenance, archiving, and disposal of digital documents and records.

5.5.1. SCOPE

This SOP covers the processes from the receipt and sorting of digital documents to their maintenance, archiving, and disposal.

5.5.2. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Receiving and classification of documents		
1. Receive and classify documents - Administrative Files: Reference materials, letters, member/investigator profiles, forms - Clinical Research Documents: Protocols, approvals, assessments, related submissions	SLMC-IERC Secretariat	Within 3 working days
Step 2. Maintenance of documents in organized folders		
A. Active Study Files		
1. Maintain and store files on Google Drive and the server, designated with blue folder icons, secured with password protection, and restricted to access by the SLMC-IERC Secretariat only	SLMC-IERC Secretariat	Within 7 working days from receipt

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. Store hard copies of documents that were received before the transition to electronic submissions in locked cabinets.	SLMC-IERC Secretariat	Within 7 working days from receipt
3. Update active study files as new submissions are received	SLMC-IERC Secretariat	Within 7 working days from receipt
B. Archived Study Files		
1. Archive completed, terminated, withdrawn, or closed-out study files on Google Drive and the server, designated with red folder icons, secured with password protection, and restricted to access by the SLMC-IERC Secretariat only	SLMC-IERC Secretariat	Within 7 working days of archiving decision
2. Store hard copies of documents that were received before the transition to electronic submissions in locked cabinets in the Archive Room	SLMC-IERC Secretariat	Within 7 working days of archiving decision
3. Retain archived files	SLMC-IERC Secretariat	For 3 years from archiving date
Step 3. Disposal/deletion of files		
1. Identify digital files that are scheduled for disposal or deletion based on three-year retention period	SLMC-IERC Secretariat	Every January and July (bi-annual check)
2. Permanently delete digital files and wipe data	SLMC-IERC Secretariat	Within 2 weeks from identification

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ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
3. Shred hard copies	SLMC-IERC Secretariat	Within 2 weeks from identification
4. Dispose dry waste after shredding	SLMC-IERC Secretariat	Within 2 weeks from identification

5.5.3. PROCEDURES

Step 1. Receiving and classification of documents

1. The SLMC-IERC Secretariat shall receive and classify documents as follows:
 - Administrative Files: Includes reference materials, letters, member and investigator profiles, and forms.
 - Clinical Research Documents: Includes protocols, ethical approvals, assessments, and related submissions.

Step 2. Maintenance of documents in organized folders

A. Active Study Files

1. All active study files shall be stored digitally in organized folders on Google Drive and the server. These digital folders will be designated with blue folder icons for easy identification, secured with password protection, and restricted to access by the SLMC-IERC Secretariat only. Active Study Files, which include files of on-going clinical research studies, shall contain:
 - a) Correspondences
 - Submission Letter
 - Notice of Action (NOA)
 - Response to NOA
 - Ethical Clearance (EC)
 - Principal Investigator's Responsibilities signed Conforme
 - SLMC-IERC Members' composition

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SOP Title: Management of Administrative and Clinical Research Protocol Files	SLMC-IERC SOP No.: SOP No. 5.4

- Notice of EC Renewal
- b) Submissions
 - Protocol
 - Investigator's Brochure
 - Informed Consent Forms
 - Case Report Forms or Data Collection Forms
 - Patient Recruitment materials/Ads/Posters
 - Principal Investigator's CV
 - GCP Certificate
 - Disclosure of Conflict of Interest
 - Insurance
 - PFDA approval
 - Amendments
 - ADR/SAE/SUSAR Reports
 - Line Listing of CIOMS/Safety Reports/SUSARS
 - Protocol Deviations/Violations reports
 - Continuing Review Reports/Progress Reports
- 2. Hard copies of documents that were received before the transition to electronic submissions will be securely stored in locked cabinets. The key to these cabinets will be kept under the custody of the SLMC-IERC Secretariat to ensure their security and confidentiality.
- 3. The active study files from time to time shall be updated as documents for specific clinical research studies are submitted by the Principal Investigator/Project Leader. These updates will ensure that all pertinent information is current and accurately reflected in the records.

B. Archived Study Files

- 1) Archived Study Files, encompassing all previously outlined documents, are files related to completed, terminated, withdrawn, or closed-out clinical research studies. They shall be stored in digital folders on Google Drive and the server, designated with red folder icons (using Google Drive's color-coding feature). These folders are secured with a password and access is restricted to the SLMC-IERC Secretariat.
- 2) For hard copies of documents that were received before the transition to electronic submissions, archived files shall be physically stored in the Archive Room. This room

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Administrative and Clinical Research Protocol Files	SLMC-IERC SOP No.: SOP No. 5.4

is accessible exclusively to the SLMC-IERC Secretariat, ensuring secure and controlled access to the archived materials.

- 3) Archived files shall be stored for three (3) years.

Step 3. Disposal or deletion of files

1. The SLMC-IERC Secretariat shall identify digital files that are scheduled for disposal or deletion based on three-year retention period.
2. All digital files marked for disposal shall be securely deleted from Google Drive and the server. This includes:
 - Permanent Deletion: Files will be removed from the recycle bin or trash folder to ensure complete removal.
 - Data Wiping: Use data-wiping tools or software to overwrite the files before deletion, ensuring that the data cannot be recovered.
 - Verification: Confirm that files have been permanently deleted and are no longer retrievable from backup or archived systems.
3. Hard copies shall be disposed of by shredding.
4. After shredding, all dry wastes shall be disposed in a black bag. *(Refer to Waste Management Policy for proper handling and disposal of waste.)*

5.5.4. REFERENCES

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

---Nothing Follows---

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Administrative and Clinical Research Protocol Files	SLMC-IERC SOP No.: SOP No. 5.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
7	03-2024 12-2024		6	Compliance with suggestions of FERCAP/PHREB surveyors 1.Change of SOP No. from 5.5 to 5.4 2.Insertion of procedures on receipt, storage, and disposal of digital files 3.Change in retention period from 5 years to 3 years 4.Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Databases	SLMC-IERC SOP No.: SOP No. 5.5

5.5.1. PURPOSE

The purpose of this SOP is to describe the procedures for managing the SLMC-IERC databases, ensuring accurate data entry, updates, and maintenance.

5.5.2. SCOPE

This SOP covers the process from data entry in the SLMC-IERC databases to maintenance of the databases.

5.5.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Encode data to the Google Sheet databases: 1. SLMC-IERC Database 2. Initial Review Database 3. Continuing/Progress Review Database 4. SAE Database 5. Protocol Deviations/Violations Database 6. Amendments Database 7. Email Communications Tracker Database 8. Query and Complaints Database	SLMC-IERC Processor and Coordinators	Within 1-3 working days of receipt
Step 2. Update the databases as needed	SLMC-IERC Processor and Coordinators	Within 1-3 working days of receipt
Step 3. Backup all Google Sheets to a secure server	SLMC-IERC Processor and Coordinators	Weekly (every Friday)
Step 4. Restrict access to authorized personnel only	SLMC-IERC Processor and Coordinators	Continual

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SOP Title: Management of Databases	SLMC-IERC SOP No.: SOP No. 5.5

5.5.4. PROCEDURES

Step 1. The SLMC-IERC Processor and Coordinators shall encode data into the following Google Sheet databases

1. SLMC-IERC Database
 - EC Reference Number
 - Protocol number (given by the Sponsor/CRO)
 - Study classification
 - Name of Principal Investigator/Contact Number/email address/ Department
 - Name of Study Coordinator/Contact Number/email address/ Department
 - Sponsor/CRO
 - Date Received/Reviewed/Approved
 - Release date of Notice of Action
 - Type of Review i.e. expedited or full-board
 - Close-out date/Termination date/Withdrawal date
 - Schedule of Continuing Review Submission i.e. progress report (*annually, semi-annually or quarterly*)
 - Ethical Clearance Renewal date
 - Remarks
2. Initial Review Database
 - SLMC-IERC Ref no.
 - Review Type (FR/ER/EX)
 - Date forwarded to reviewers
 - Primary Reviewer/ Independent Consultant/ Independent Consultant
 - Date received
 - ISRC received date
 - Date
 - NOA
 - Date issued NOA
 - Ethical Clearance
 - Date issued Ethical Clearance

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SOP Title: Management of Databases	SLMC-IERC SOP No.: SOP No. 5.5

3. Continuing/Progress Review Database

- Date of Submission
- SLMC-IERC Ref no.
- Study Site/ Review Type (FR/ER/EX)
- Study Classification (SIT IIT)
- Date of Approval
- Date Close Out
- Principal Investigators/ Contact Person/ Email/ Institute
- Type of Document Received
- CRRF STATUS
- Reviewers (Primary/Member in charge)
- Date received review
- NOA Date
- Response to NOA
- Review Date
- IERC Action / Remarks
- Monitoring Visits
- Remarks

4. SAE Database

- Received date/acknowledge
- SLMC-IERC Ref #
- SAE Diagnosis
- Subject #/initial
- Date of event /experience
- Date of report
- Relationship to study drug and expectedness
- Severity
- Admitted (SLMC/Other Hospital)
- Outcome
- Reviewers (Primary/Pharmacologist/Member in charge)
- Type of Report
- Action
- Date received of review (Primary/Pharmacologist)
- Remarks

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- Comments
- Date included in Agenda
- Date issued NOA

5. Protocol Deviations/Violations Database

- Received date/acknowledge
- SLMC-IERC Ref #
- SIT/IIT
- Name of Principal Investigator
- Characterization and Detail Specific Violation
- Subject #/initial
- Date occurred
- Date of Site Awareness
- Date reported
- Name of Reviewers
- Comments of Reviewers
- Review Date
- Remarks
- IERC Action
- Date Issued NOA

6. Amendments Database

- SLMC-IERC Ref no.
- Date of submission
- Principal Investigators
- Department/Institute
- Submitted by/Received by
- Documents submitted/Amendment details
- Name of Reviewers
- Date of Review
- Date of Notice of Action (if applicable)
- Date of Response (if applicable)
- Date of approval/Approval Status
- Date included in IERC Agenda

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7. Email Communications Tracker Database.

- Date of encoding or logging
- New or response from PI/Project leader
- Date of email
- Protocol-related or non-protocol-related
- EC Reference Number, if applicable
- Name of sender
- Email recipient
- Email subject
- Email content/summary
- SLMC-IERC Secretariat Coordinator responsible
- Date of email response
- Remarks

8. Query and Complaints Database

- Variable Name
- Entry Number
- Date Received
- Type of Inquiry
- Source
- EC Reference No.
- Submitter
- Contact No.
- Email Address
- Description
- Category
- Assigned To
- Status
- Resolution Date
- Resolution Summary

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Step 2. The SLMC-IERC Processor and Coordinators shall update the database as needed, ensuring all data entries are accurate

Step 3. The SLMC-IERC Processor and Coordinators shall regularly backup all Google Sheets to a secure server to prevent data loss.

Step 4. The SLMC-IERC Processor and Coordinators shall restrict access to databases to authorized SLMC-IERC personnel only.

5.5.5. REFERENCE

Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.

---Nothing Follows---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE		Document Type: MANUAL
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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory		Revision Effective Date: April 1, 2025
SOP Title: Management of Databases		SLMC-IERC SOP No.: SOP No. 5.5

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
6	06-2022		6	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
7	03-2024 12-2024		7	Compliance with suggestions of FERCAP/PHREB surveyors 1. Added detailed entries for multiple databases including Initial Review, Continuing/Progress Review, SAE, Protocol Deviations/Violations, Amendments, Email Communications Tracker, and Query and Complaints 2. Updated responsibilities 3. Added backup procedures 4. Change of Flowchart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Management of Databases	SLMC-IERC SOP No.: SOP No. 5.5

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: PREPARING SOPs and GUIDELINES FOR THE SLMC-IERC	SLMC-IERC SOP No.: SOP No. 6

6. PREPARING SOPs and GUIDELINES FOR THE SLMC-IERC

SOPs are vital in ensuring the efficiency, transparency, and consistency of SLMC-IERC operations. The SOP manual needs to be periodically reviewed to determine the need for revision or new SOPs in order to respond to emerging operational issues of the SLMC-IERC.

SOP No. 6 outlines the following specific SOPs:

- SOP 6.1 Writing and Revising SOPs
- SOP 6.2 Guidelines in Preparing SOPs



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☒ Regulatory	Revision Effective Date: April 1, 2025
SOP Title: Writing and Revising SOPs	SLMC-IERC SOP No.: SOP No. 6.1

6.1.1. PURPOSE

This SOP provides a clear and systematic approach to the writing, formatting, approval, publication, and revision of SOPs. It outlines the procedures for the orderly management of SOP documentation, to ensure that all operating procedures remain current, reflective of best practices, and compliant with applicable standards.

6.1.2. SCOPE

This SOP covers the entire lifecycle of formulating and updating SOPs within SLMC-IERC, from proposal through approval, adoption, and distribution. It outlines the steps for proposing, drafting, reviewing, approving, and disseminating new or revised SOPs.

6.1.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. Identifying SOPs for Formulation or Amendment		
1. Propose new or amended SOP	SLMC-IERC Chair, Members, Secretariat, SOP Team	As needed
2. Include rationale and present proposal in SLMC-IERC regular meeting	SLMC-IERC Proponent	During full board meeting
3. Decide on proposal by consensus	SLMC-IERC Members	During full board meeting
Step 2. Writing, Formulating, Formatting, and Approving SOPs		
1. Designate review/drafting team	SLMC-IERC	As needed / during regular review cycle

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SOP Title: Writing and Revising SOPs	SLMC-IERC SOP No.: SOP No. 6.1

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
2. Draft/revise SOP using standard format (SOP 6.2)	Designated SOP Team	Within 2–8 weeks after designation
3. Include final SOP draft in meeting agenda for approval	SLMC-IERC Secretariat	Prior to next regular meeting
4. Review and approve SOP draft by consensus	SLMC-IERC Members	During SLMC-IERC regular meeting
5. Submit approved SOP Manual for routing and signature (Associate Director for R&B ORI, R&B Head, Chair, Institutional Heads)	Associate Director for R&B ORI	Within 2 weeks of SLMC-IERC approval
Step 3. Archiving and Filing System		
1. Store signed and dated controlled copy in secure digital folder	SLMC-IERC Secretariat	Immediately after all signatures
Step 4. Effectivity and Implementation		
1. Implement newly approved or amended SOP	SLMC-IERC Chair, Members, Secretariat	Immediately upon CEO approval
2. Distribute soft copies of the approved SOP	SLMC-IERC Secretariat	Within 1–2 working days post-approval

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SOP Title: Writing and Revising SOPs	SLMC-IERC SOP No.: SOP No. 6.1

6.1.4. PROCEDURES

Step 1. Identifying SOPs for Formulation or Amendment

1. The SLMC-IERC Chair or Members shall propose new SOPs or amendments to existing ones.
2. The proponent shall include the rationale for the new SOP or amendment in the proposal and discuss it at an SLMC-IERC regular meeting.
3. The SLMC-IERC will decide on the proposal by consensus.

Step 2. Writing, Formulating, Formatting, and Approving SOPs

1. The SLMC-IERC shall designate a team to regularly review its set of SOPs and guidelines to determine its continuing relevance and effectiveness to its operations. This team is tasked with drafting or revising SOPs.
2. Draft all SOPs in the standard format outlined in SOP 6.2, "Guidelines for Preparing SOPs." A comprehensive revision history for all amended SOPs, including the Revision Date and Version Number, shall be maintained.
3. The final draft of any new or revised SOP shall be included in the agenda for the next SLMC-IERC regular meeting for formal approval through consensus.
4. The SLMC-IERC Members shall review and approve the draft by consensus during the meeting.
5. The Associate Director for R&B Office of Research Integrity shall submit the revised SOP Manual to Hospital Operations for routing and signature of Associate Director for R&B ORI, Head of R&B, SLMC-IERC Chair, and other designated institutional officers.

Step 3. Archiving and Filing System

1. The SLMC-IERC Secretariat shall store the signed and dated controlled copy of the updated SOP in the designated secure digital folder.

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SOP Title: Writing and Revising SOPs	SLMC-IERC SOP No.: SOP No. 6.1

Step 4. Effectivity and Implementation

1. A new or revised SOP will become effective immediately after the President and CEO approves it. The SLMC-IERC Chair, Members, and Secretariat are responsible for implementing the newly approved or amended SOP.
2. The SLMC-IERC Secretariat shall disseminate soft copies of the approved SOP to all Members and other authorized personnel.

6.1.5. REFERENCES

- Philippine Health Research Ethics Board. (2020). *Standard Operating Procedures Workbook for Ethics Review Committees*. PHREB.
- Philippine Health Research Ethics Board. (2022). *National Ethical Guidelines for Research Involving Human Participants*. Department of Science and Technology - Philippine Council for Health Research and Development.
- World Health Organization. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. World Health Organization.

---Nothing Follows---

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SOP Title: Writing and Revising SOPs		SLMC-IERC SOP No.: SOP No. 6.1

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SLM-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	07-2018		4	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022
7	03-2024 12-2024		5	Compliance with suggestions of FERCAP/PHREB surveyors 1. Change of flowchart to workflow with timelines 2. Update of References 3. Added routing through ORI Head, R&B Head, Chair, Institutional Heads prior to CEO approval	Pacifico Eric E. Calderon, MD, MBeth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025

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SOP Title: Writing and Revising SOPs	SLMC-IERC SOP No.: SOP No. 6.1

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP Title: Guidelines in Preparing SOPs	SLMC-IERC SOP No.: SOP No. 6.2

6.2.1. PURPOSE

This SOP standardizes the process of preparing and writing SOPs within the SLMC-IERC, to ensure consistency in format, content, and presentation.

6.2.2. SCOPE

This SOP covers the standardization process for the SOP format, content, and numbering system used by the SLMC-IERC.

6.2.3. WORKFLOW

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1. SLMC-IERC SOP Manual Structure		
1. Structure the SOP Manual according to SLMC standards, ensuring inclusion of required sections (e.g., Introduction, SOPs, References, etc.)	SLMC-IERC Chair, SOP Team	Concurrent with SOP drafting or revision
Step 2. SLMC-IERC SOP Standard Format and Content		
1. Apply the standard header and footer format (logo, titles, codes, pagination, etc.)	SLMC-IERC Secretariat	At the time of drafting each SOP
Step 3. Content Components		
1. Ensure each SOP includes: Purpose, Scope, Workflow, Procedures, References, and Document History	SLMC-IERC Chair, SOP Team	At the time of drafting each SOP

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SOP Title: Guidelines in Preparing SOPs	SLMC-IERC SOP No.: SOP No. 6.2

Step 4. Content Detailing		
1. Draft and detail each component (e.g., Purpose, Scope, Workflow mapping, Procedures, References, History)	SLMC-IERC SOP Writing Team	At the time of drafting each SOP
Step 5. Numbering and Versioning		
1. Assign a unique document code, such as SLMC-IERC SOP No. XX, to each SOP	SLMC-IERC SOP Writing Team	At the time of drafting each SOP
2. Update effectivity date for revised SOPs	SLMC-IERC SOP Writing Team	Upon finalization
Step 6. SOP Manual Signatory Process		
1. Prepare draft SOP Manual	Associate Director for R&B ORI, SLMC-IERC SOP Writing Team	As needed
2. Review draft SOP Manual for content and compliance	SLMC-IERC Chair and Vice-Chair	Within 5 working days from submission
3. Recommend for approval of Head of R&B, Chief Medical Officer, Chief of Hospital Operations	Associate Director for R&B ORI	Within 10 working days
4. Grant final approval	President & CEO	Within 10 working days after recommendation

6.2.4. PROCEDURES

Step 1. SLMC-IERC SOP Manual Structure

1. The SLMC-IERC SOP Manual shall adhere to SLMC standards for quality manuals and include the following sections:
 - General Document Review and Revision History



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SOP Title: Guidelines in Preparing SOPs	SLMC-IERC SOP No.: SOP No. 6.2

- Signature Page
- Table of Contents
- Introduction
- Objective
- Responsibilities
- Standard Operating Procedures (SOPs)
- References
- Attachments (Forms and Templates)
- Acronyms
- Definitions of Terms
- Glossary

Step 2. SLMC-IERC SOP Standard Format and Content

1. All written SOPs should adhere to a standard format, described as follows:
 - i. A header indicating the following:
 - SLMC logo in the upper middle portion
 - INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE in bold upper case letters as Title of the Manual
 - MANUAL in bold upper case letters as Document Type
 - System box ticked as Level of the Manual
 - Document Code
 - Research and Regulatory boxes ticked as Category of the Manual
 - Effectivity date
 - Title of the specific SOP
 - SOP number
 - ii. and a footer indicating pagination.

Step 3. Each SOP should contain the following parts:

- Purpose
- Scope
- Workflow
- Procedures
- References
- Document history



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Step 4. Each SOP details its content as follows:

- Purpose - This articulates the aim of the SOP.
- Scope - This describes the range of activities and processes the SOP covers.
- Workflow - This visually maps the procedure steps and assign responsibilities
- Procedures - This provides a step-by-step account of the procedure outlined in the Flow Chart.
- References – This provides the list of any relevant documents or guidelines used
- Document History – This provides tracking of revisions and updates.

Step 5. Numbering and Versioning of SOPs

1. All SOPs shall be assigned a unique document code, such as SLMC-IERC SOP No. XX, to each SOP. Only the final version of the SOP shall be assigned a document code.
2. A revised SOP shall have a new effectivity date.

Step 6. Signatory Process for the SLMC-IERC SOP Manual

1. The development and approval of SOPs involve several key personnel, each with specific responsibilities:
 - a) The SOP Manual is prepared by the Associate Director for R&B Office of Research Integrity and/or a designated Member of the SLMC-IERC.
 - b) Following preparation, the SOP Manual is reviewed for content and compliance by the SLMC-IERC Chair and Vice-Chair.
 - c) After review, the SOP Manual is recommended for approval by the Head of R&B, the Assistant Chief Medical Officer, and the Chief of Hospital Operations.
 - d) Final approval is granted by the President & CEO.

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6.2.5. REFERENCES

Philippine Health Research Ethics Board. (2020). *Standard Operating Procedures Workbook for Ethics Review Committees*. PHREB.

Philippine Health Research Ethics Board. (2022). *National Ethical Guidelines for Research Involving Human Participants*. Department of Science and Technology - Philippine Council for Health Research and Development.

World Health Organization. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. World Health Organization.

---Nothing Follows ---

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019

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DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
6	06-2022		6	1. Integrated the SLMC format for Manuals (Header, signatories)	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	Jun 2022
7	03-2024 12-2024		7	Compliance with suggestions of FERCAP/PHREB surveyors 1. Shortened the scope statement 2. Added SLMC format of quality manual 3. Update of signatories 4. Change of Flowhart to Workflow with timelines	Pacifico Eric E. Calderon, MD, MBEth, MEd SLMC-IERC Member Cynthia A. Mapua, MSc Associate Director for Center for Clinical Research Research and Biotechnology Gelza Mae A. Zabat, MD SLMC-IERC Chair (Apr 2023-Mar 2025)	Mylene U. Cornel, MD SLMC-IERC Chair	May 2024 April 2025



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5. ATTACHMENTS

FORM # 01A	Agreement on Confidentiality and Conflict of Interest Form for SLMC-IERC Members
FORM # 01B	Agreement on Confidentiality and Conflict of Interest Form for External/Independent Consultant
FORM # 01C	Disclosure of Conflict of Interest for Principal Investigator/ Study Team
FORM # 02A	Initial Submission Form for Research
FORM # 02B	Checklist of Clinical Trials Initial Submission Form
FORM # 02C	Initial Protocol Review Acknowledgment Form
FORM # 02D	SLMC-IERC Initial Review Form
FORM # 02E	Ethics Review Form for Protocol
FORM # 02F	Ethics Review Form for Informed Consent
FORM # 02G	Ethics Review Form for External /Independent Consultant
FORM # 03A	Ethical Clearance
FORM # 03B	Response to Notice of Action Evaluation Form
FORM # 04A	Continuing Review/Progress Report Form
FORM # 04B	Final Report Form
FORM # 04C	Termination Report Form
FORM # 04D	Renewal Ethical Clearance
FORM # 04E	ADR/SAE/SUSAR Report Form
FORM # 04F	Protocol Deviation/Violation Form
FORM # 04G	Protocol Amendment Form
FORM # 04H	Clinical Research/Site Monitoring Form
FORM # 04I	ICF Clinical Monitoring Form (<i>Attachment to Clinical Research/Site Monitoring Form</i>)
Template # 01A	Letter of Appointment Template
Template # 01B	SLMC-IERC Roles and Responsibilities Template (<i>Attachment to SLMC-IERC Appointment</i>)
Template # 01C	SLMC Institutional Ethics Review Committee Composition
Template # 02	Application of Waiver of Informed Consent
Template # 03A	Letter of Exemption from Review
Template # 03B	Notice of Action
Template # 03C	Summary of Revisions
Template # 03D	SLMC-IERC Reviewer Composition Template

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Template # 03E	Principal Investigator and Study Team Acknowledgment of Responsibilities
Template # 03F	Elements for Presentation during Full Board Review of Clinical Research Protocols
Template # 03G	SLMC-IERC Meeting Attendance Sheet
Template # 03H	Response to Query or Complaint Template
Template # 04A	Memo (For Renewal of Ethical Clearance)
Template # 04B	SAE Notice of No Action Template
Template # 04C	PD/PV Notice of No Action Template
Template # 04D	Notice of Approval Template
Template # 04E	Clinical Research/Site Monitoring Notice
Template # 05A	Agenda Template
Template # 05B	Minutes of Meeting Template



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SOP FORM TITLE: Agreement on Confidentiality and Conflict of Interest Form for SLMC-IERC Members	SOP FORM NO.: FORM # 01A



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

As a Member of the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC), I may be provided with confidential information and documentation (*referred to here as "Confidentiality Information"*). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member.

Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

My signature below signifies that I have read and accept the terms and conditions set in this agreement.

Printed Name and Signature of
SLMC-IERC Member

Date

Printed Name and Signature of Head
Research and Biotechnology Group

Date

*All members of St. Luke's Medical Center Institutional Ethics Review Committee are required to sign and date this **Agreement on Confidentiality and Conflict of Interest** before they assume their duties in the committee. The Original signed and dated copy of this Agreement shall be kept on file in the member's binder under the Custody of the SLMC-IERC Secretariat. A copy will be given to each for his own records.

SLMC-IERC FORM # 01A V 05/2024 (IERC Member)



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP FORM TITLE: Agreement on Confidentiality and Conflict of Interest Form for External/Independent Consultant	SOP FORM NO.: FORM # 01B



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

As a Subject Matter Expert or External Independent Consultant of the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC), I may be provided with confidential information and documentation (*referred to here as "Confidentiality Information"*). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the SLMC-IERC Chairperson or Secretariat upon termination of my functions as an Independent Consultant.

Furthermore, I shall immediately inform the Chairperson whenever I have conflict of interest in a study I will evaluate.

My signature below signifies that I have read and accept the terms and conditions set in this agreement.

 Printed Name and Signature of
Independent Consultant

 Date

 Printed Name and Signature of Chair
SLMC Institutional Ethics Review Committee

 Date

 SLMC-IERC FORM # 01B V 05/2024 (Consultant)



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Effective Date: April 1, 2025
SOP FORM TITLE: Agreement on Confidentiality and Conflict of Interest Form for External/Independent Consultant	SOP FORM NO.: FORM # 01B

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Disclosure of Conflict of Interest for Principal Investigator/Study Team	SOP FORM NO.: FORM # 01C

St. Luke's Medical Center We love life.	INSTITUTIONAL ETHICS REVIEW COMMITTEE
DISCLOSURE OF CONFLICT OF INTEREST	
Please check the appropriate box and print clearly. ☐ Principal Investigator ☐ Sub- or Co-investigator ☐ Study Coordinator or Research Assistant ☐ SLMC-IERC External/Independent Consultant GIVEN NAME _____ FAMILY NAME _____ MI _____ Contact No.: _____ Email _____ PROTOCOL NO.: _____ PROTOCOL TITLE: _____ _____ _____ _____	
Please answer each of the question below by CHECKING THE APPROPRIATE BOX. If you check YES to any question you must attach details of the disclosable financial arrangements. Insert and print clearly the name of the Sponsor/CRO (for sponsor-initiated trials) or Collaborator/Supplier (for SLMC investigator-initiated research studies) in the questions.	
1. Do you, your spouse, or your dependent children participate in any financial arrangement with the Sponsor/CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study, whereby the value of the compensation could be influenced by the outcome of the study (i.e., could be higher for a favorable outcome than for an unfavorable outcome)?	Yes ☐ No ☐
2. During the time you are conducting the study and for one (1) year following completion of the study, will you, your spouse or dependent children or your institution (to the extent used to support your activities) receive any significant payments of other sorts from the Sponsor/CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study which is exclusive of the costs of conducting the clinical study?	Yes ☐ No ☐
3. Do you, your spouse or dependent children, hold any proprietary interest (property or other financial interest) in the product. Proprietary interest would include, but not limited to, a patent, trademark, copyright or licensing agreement.	Yes ☐ No ☐
4. Do you, your spouse or dependent children, hold any significant interest in the Sponsor/ CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study such as any ownership interest (e.g., stock ≥ PHP 500,000.00), stock options or other financial interest?	Yes ☐ No ☐
5. Are you a co-author or adviser of the Principal Investigator/Project Proponent(s) for this clinical study? (For SLMC-IERC External/Independent Consultant only)	Yes ☐ No ☐
I declare that the information provided on this form, is to the best of my knowledge and belief, true, correct and complete. Furthermore if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year following completion of the study as per site closure letter, I will promptly notify St. Luke's Institutional Medical Center Ethics Review Committee.	
SIGNATURE _____	DATE (MMM-DD-YYYY) _____
SLMC-IERC Form # 01C V05/2024	



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SOP FORM TITLE: Initial Submission Form for Research	SOP FORM NO.: FORM # 02A



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

Initial Submission Form for Research

Principal Investigator/Project Leader:	Institute/Department:
Type of Research (Kindly check what applies)	
☐ Sponsor-Initiated Trial (SIT) For Pharmaceuticals, CROs, AROs ☐ Drug ☐ Phase 1 ☐ Medical device ☐ Phase 2 ☐ Procedure ☐ Phase 3 ☐ Observational ☐ Phase 4 ☐ Others, specify:	☐ Investigator-Initiated Trial (IIT) For Consultant/Fellow/Resident/Faculty/Personnel/Student ☐ Biomedical Study ☐ Systematic review and meta-analysis ☐ Health Operations Research ☐ Registry/Databank ☐ Public Health Research ☐ Animal Study ☐ Social/Behavioral Research ☐ Plant Study ☐ Case study/report ☐ Others, specify:
Email address:	Contact Nos: Office: Mobile:
Sponsor:	CRO:
Protocol Title:	

INSTRUCTIONS:
 Please indicate in the columns below whether or not elements stated in the checklist for specific documents (protocol or ICF) have been included (Y=Yes; N=No; NA=Not applicable). If yes, state the page and paragraph where the element can be found.

NOTE:
 The following checklist includes the ICH GCP E6 Guideline for Good Clinical Practice recommendations for Protocol content and Informed Consent forms. Supporting documents to use as basis for review may include the Investigator's Brochure (IB), protocol, protocol amendment(s) and other documents, if applicable.

STUDY PROTOCOL	Y	N	NA	Page & Paragraph Nos.
1. General Information				
1.1. Protocol title, protocol number, version number, version date.				
1.2. Name(s) and affiliation(s) of Principal Investigator and/or Project Leader, Co- or Sub-Investigator(s), Co-Project Leaders				
1.3. Name and address of the sponsor and Contract Research Organization (CRO)				
2. Brief Description (summary of all the central elements of the protocol, e.g. rationale, objectives, methods, populations, time frame, and expected outcomes)				
3. Background Information				
3.1. Significance of the Project (justification for the project – where the results will be used, who will use the results)				
3.2. Rationale for doing the study (reasons for conducting the research in light of current knowledge, stating the need/problem that is the basis of the project, the cause of this problem, and its possible solutions)				
3.3. Background Information and Brief Literature Review (narrative of the status of research in the specific topic, critically evaluating existing knowledge, non-clinical study findings, new findings, current protocol, and the gaps that need to be addressed;)				
3.4. Description of the potential risks and benefits of the study				
4. Objectives				
4.1. Primary objectives (the main goals of the study)				
4.2. Secondary objectives (additional goals to be investigated)				

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STUDY PROTOCOL	Y	N	NA	Page & Paragraph Nos.
5. Trial Design				
5.1. Study design (<i>description of study design to be conducted, e.g. case study/report, case series, cross-sectional, case-control, cohort, or experimental; double-blind, placebo-controlled, parallel design</i>)				
5.2. For Experimental Studies: Schematic diagram of study design, procedures and stages				
5.3. For Experimental Studies: Measures taken to minimize/avoid bias (<i>e.g. randomization, blinding</i>)				
5.4. Time period and Target Population (<i>clear description of study duration, target population (e.g. biological, social, or behavioral attributes) place and time</i>)				
6. Eligibility Criteria				
6.1. Clear description of both inclusion and exclusion criteria for participant selection				
6.2. Methods used to determine a subject's eligibility (<i>information reported by the subject, medical record review, results of screening assessment (e.g. questionnaire diaries, etc.)</i>)				
7. Operational definitions (<i>definitions of diseases, outcomes, procedures & other relevant conditions in terms of definitive diagnosis or how they will be measured.</i>)				
8. Description of Study Procedure				
8.1. Expected duration of subject participation				
8.2. Description of the sequence and duration of all study periods including follow-up, if any.				
8.3. Description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of study, and entire study.				
8.4. Accountability procedures for the investigational product(s), including the placebo(s)/sham procedures and comparator(s), if applicable.				
8.5. Identification of any data to be recorded directly on the case report forms (CRF) or data collection forms				
8.6. Data will be collected using specific tools like a CRF or data collection form, questionnaire. Format (e.g., paper-based, electronic) and frequency of data collection is described.				
8.7. Method for collection, storage, and analysis of biological specimens, if applicable				
8.8. Statement on future use of collected specimens, if applicable				
9. Subject Recruitment and Withdrawal of Subjects				
9.1. Subject recruitment methods used to enroll participants				
9.2. Subject withdrawal criteria and procedures (<i>including when and how to withdraw subjects, data collection for withdrawn subjects, whether and how subjects will be replaced, and follow-up procedures for withdrawn subjects</i>)				
10. Treatment of Subjects				
10.1. For Experimental Studies: Description of interventions (drug, biologics, procedures, device), dosage, schedule, route of administration, and follow-up period(s)				
10.2. For Experimental Studies: Permitted and non-permitted medications before and/or during the trial				
10.3. For Observational Studies: Description of interventions (if applicable)				
10.4. Procedures for monitoring subject compliance				
11. Assessment of Efficacy and Safety				
11.1. Efficacy parameters (<i>specific measures used to assess the study's effectiveness</i>)				
11.2. Methods and timing for assessing, recording, and analyzing efficacy parameters				
11.3. Safety parameters (<i>specific measures used to assess potential risks</i>)				
11.4. Methods and timing for assessing, recording, and analyzing safety parameters				
11.5. Procedures for eliciting reports and for recording and reporting Adverse Events (AEs) and intercurrent illnesses (unexpected health problems)				
11.6. Type and duration of the follow-up of subjects after adverse events.				



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		INSTITUTIONAL ETHICS REVIEW COMMITTEE		
STUDY PROTOCOL	Y	N	NA	Page & Paragraph Nos.
12. Statistics				
12.1. Description of the statistical methods to be employed, including:				
a. Sampling design (<i>how participants will be selected for analysis</i>)				
b. Statistical analysis plan (<i>specific methods used to analyze data</i>)				
c. Level of significance (<i>the threshold for considering results statistically significant</i>)				
d. Criteria for termination of the trial (<i>predefined conditions to stop the study</i>)				
e. Procedures for accounting for missing, unused, and spurious data (<i>handling incomplete or inaccurate data</i>)				
f. Procedures for reporting any deviations from the original statistical plan and justification for deviation				
12.2. Number of subjects planned to be enrolled (<i>including justification for sample size based on power analysis and clinical relevance</i>)				
12.3. Selection of subjects to be included in the analyses (<i>e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects</i>)				
13. Access to Data/Documents, Data Handling and Recordkeeping				
13.1. Statement ensuring access to source data/documents for trial-related monitoring, audits, review by St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC), and regulatory inspections				
13.2. Description of data handling and recordkeeping processes and measures to be taken, including:				
a. Confidentiality protections				
b. Sharing of data				
c. Storage and archiving of data				
d. Destruction of data after the retention period				
14. Quality Control and Quality Assurance				
14.1. Description of periodic monitoring visits during the study to ensure that the protocol and GCPs are being followed				
15. Ethics				
15.1. Ethical issues stated in the protocol and how these issues shall be addressed (<i>e.g. review of management of conflict of interest arising from financial, familial or proprietary considerations of the PI, spouse or the study site; informed consent process</i>)				
15.2. Statement on how, when and where Informed Consent/assent process shall be conducted.				
15.3. Name and Title of the investigator(s) who is (are) responsible for conducting the trial and the address and telephone number(s) of the trial site(s).				
15.4. Name and Title of the Study Team (investigators, research coordinators, etc.)				
16. Financing and Insurance				
16.1. Financing and insurance arrangements if not addressed in a separate agreement				
17. Publication Policy				
17.1. Publication policy if not addressed in a separate agreement.				
18. Involvement of Vulnerable Subjects				
18.1. Statement on the involvement of vulnerable subjects (<i>e.g., children, pregnant women</i>) in the clinical trial/study				
19. Advertisement materials				
19.1. Availability of advertisement material(s) used for subject recruitment				

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REVIEW COMMITTEE**

INFORMED CONSENT FORM	Y	N	NA	Page & Paragraph Nos.
1. General Information				
1.1. Protocol Title and Protocol Number				
1.2. ICF version number and version date				
1.3. Statement that study has been reviewed and approved by St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC)				
2. Introduction				
2.1. Statement that the trial/study involves research				
2.2. Clear and concise explanation of the study's objectives and why the research is being conducted				
3. Study Procedures				
3.1. Description of study procedures, including:				
a. Observational or interventional nature of the study				
b. Randomization and/or blinding procedures, if applicable				
c. Frequency and duration of participation				
d. Potential risks and discomforts (including delayed AEs)				
e. Specimen to be collected and the purpose.				
3.2. Subject's responsibilities (Expected duration of the study and length of the individual's commitment during the duration of the study)				
4. Benefits and Risks				
4.1. Reasonably foreseeable risks/inconveniences to subject/embryo/ fetus/nursing infant or others				
a. Statement to address the foreseeable risks to the fetus or nursing infant of participant of child-bearing potential				
b. Risks from allowable use of placebo				
4.2. Description of potential benefits to the subject or to others, which may reasonably be expected from the research. If none is expected subject must be informed.				
5. Disclosure of the alternative procedure(s)/treatments, if applicable				
5.1. Brief description of any standard or established treatments available outside of the study.				
5.2. Description of potential benefits and risks associated with these alternatives, to the extent known.				
6. Compensation and Costs				
6.1. Anticipated prorated payment, if any, to the subject for participating in the study				
6.2. Anticipated expenses, if any, to the subject for participating in the study.				
6.3. Compensation/treatment available for trial-related injury, if applicable				
7. Voluntary Participation and Withdrawal				
7.1. Statement that subject's participation is voluntary				
7.2. Statement that the subject may refuse to participate or withdraw at any time without penalty or loss of benefits				
7.3. Statement that the investigator/sponsor may terminate the study due to safety concerns, non-compliance, etc.				
8. Confidentiality				
8.1. Statement that identifying records will be kept confidential and will not be made publicly available. If the results are published the subject's identity will remain confidential.				
8.2. Explanation of how data will be anonymized or coded				

SLMC-IERC Form #02A V05/2024

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Initial Submission Form for Research	SOP FORM NO.: FORM # 02A

 St. Luke's Medical Center <i>We love life.</i>		INSTITUTIONAL ETHICS REVIEW COMMITTEE			
INFORMED CONSENT FORM		Y	N	NA	Page & Paragraph Nos.
8.3. Statement that specimens may be used for future research and referencing a separate document that details specific uses and participant rights, if applicable. a. The separate document is clear, concise, and readily available to participants.					
9. Access to Records and Information					
9.1. Statement on Granting Access to Subject's Records for Verification (by monitors, auditors, SLMC-IERC, and regulatory authorities)					
9.2. Statement that subject or the legally acceptable representative will be informed in a timely manner if information becomes available that might influence the subject's willingness to stay in the trial/study.					
10. Contact Information					
10.1. Contact information for study team for further information regarding the trial/study and the rights of trial/study subjects, and whom to contact in the event of trial/study – related injury					
10.2. Contact information for trial/study – related injury					
11. Additional Information for Vulnerable Populations					
11.1. For children: Use of an Assent Form in addition to parental consent					
11.2. For pregnant women or partners of male participants					
a. Description of unknown effects on the fetus/infant and potential risks based on available knowledge.					
b. Separate consent form for pregnant women detailing fetal/infant risks.					
c. Description of any additional monitoring for pregnant women/partners and infant follow-up plans (if applicable).					
d. Right to withdraw at any time, even if pregnancy occurs during the study.					
e. Statement the subject's identity will remain confidential but has limitations for fetal/infant information reporting.					
12. English and Filipino translations of ICFs					
12.1. Use of clear and understandable language (grade 6 reading level) for both English and Filipino translations					
12.2. Filipino translation aligns with English version					
ACCOMPLISHED BY:					
Printed Name and Signature:		Designation:		Date:	



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Checklist of Clinical Trials Initial Submission Form	SOP FORM NO.: FORM # 02B



Research and Biotechnology Center for Clinical Trials
Checklist of Clinical Trials Initial Submission
 For sponsor-initiated researches

DATE:

☐ Letter of intent addressed to SLMC-IERC Chair
 <Name of Chair>
 Chair, Institutional Ethics Review Committee
 St. Luke's Medical Center

Kindly send to: <email of R&B CCT Coordinator> and ethicsreview@stlukes.com.ph

Soft copy of the following attachments:

☐ Clinical Study Protocol
☐ Informed Consent Forms (English and Filipino with Certificate of Filipino translation).
☐ Case Report Forms
☐ Investigator's Brochure
☐ Certificate of Insurance and Insurance Policy (**Ethical Clearance will not be released without the Policy**)

Copies of the following (If applicable):

☐ Subject Worksheets/Patient Diary/Alert Cards (English and Filipino versions), Questionnaires (English and Filipino Versions)
☐ **Philippine Food and Drug Administration Approval (Provide a certificate from PFDA if not Applicable)**
☐ Pharmacokinetics
☐ Certificate of Product Registration in the Philippines for Post Marketing Surveillance Studies (PMSS)
☐ Other related study materials (e.g. Advertisement) _____

SLMC-IERC Forms

☐ SLMC-IERC Form #01C Disclosure of Conflict of Interest FORM for Study Team (**to be filled out and signed by the Study team (PI/Sub-I/Study Coordinator/RA)**)
☐ SLMC-IERC Form #02A Initial Submission Form for Clinical Trial/Research (**to be filled out and signed by the PI**)
☐ SLMC-IERC Form #02C Initial Protocol Review Acknowledgment Form (**to be filled out and signed by the PI**)
☐ Curriculum Vitae of Investigators and Study Team

☐ GCP Certificate of Investigators and Study Team (**need to submit an attestation if taken online**)
 (**Please see attached Memo and Template**)

☐ Updated PRC License of Investigators and Sub-Investigators

☐ **Delegation of Authority from the Sponsor**

☐ **LICENSE TO OPERATE to conduct a CLINICAL TRIAL**

Note: If the dossier is incomplete, the SLMC-IERC (St. Luke's Medical Center-Institutional Ethics Review Committee) Secretariat will not accept the submission. Only complete dossier will be forwarded to SLMC-IERC and will be scheduled for review.

For protocols only awaiting approval from the PFDA, the SLMC-IERC can conduct a parallel review; however, the issuance of Ethical Clearance shall be withheld until completion of said requirement.

**** The mobile number of the Principal Investigator should be included in the ICF, Patient Card and Patient Diary aside from the clinic's phone number.**

Received By:
Date:

SLMC-IERC Form #02B V05/2024



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Checklist of Clinical Trials Initial Submission Form	SOP FORM NO.: FORM # 02B

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: APRIL 2025
SOP FORM TITLE: Initial Protocol Review Acknowledgment Form	SOP FORM NO.: FORM # 02C

 St. Luke's Medical Center <i>We love life.</i>		INSTITUTIONAL REVIEW COMMITTEE	
INITIAL PROTOCOL REVIEW ACKNOWLEDGMENT FORM			
Research/EC Reference No.:		SUBMISSION DATE:	
Type of Research (Kindly check what applies)			
☐ Sponsor-Initiated Trial (SIT)-Pharmaceuticals, CROs, ARGs ☐ Clinical Trial ☐ Phase 1 ☐ Drug ☐ Phase 2 ☐ Medical device ☐ Phase 3 ☐ Procedure ☐ Phase 4 ☐ Observational ☐ Others		☐ Investigator-Initiated Trial (IIT)-Consultant/Fellow/Resident/Faculty/Personnel/Student ☐ Interventional clinical research ☐ Public Health Research ☐ Animal Study ☐ Drug ☐ Social/Behavioral Research ☐ Plant Study ☐ Medical device ☐ Case study/report ☐ Others: ☐ Procedure ☐ Systematic review and meta-analysis ☐ Biomedical Study ☐ Registry/Databank ☐ Health Operations Research	
STUDY TITLE:			
PRINCIPAL INVESTIGATOR/PROJECT LEADER:	CONTACT #:	EMAIL:	INST/DEPT/GROUP:
SUB-INVESTIGATOR/FELLOW/RESIDENT:	CONTACT #:	EMAIL:	INST/DEPT/GROUP:
RA:	OFFICE TEL./FAX NO.	MOBILE NO.:	EMAIL:
Documents Received <i>(Pls. check all that applies. Write "NA" if not applicable)</i>		VERSION/DATE	REMARKS
☐ Letter of Endorsement from Inst/Dept Research Committee Head			
☐ Technical Review Forms signed by Research Committee Reviewers			
☐ Protocol			
☐ Investigator Brochure			
☐ Informed Consent Form(s) <i>(English)</i>			
<i>(Filipino)</i>			
☐ Pharmacokinetics ICF <i>(English)</i>			
<i>(Filipino)</i>			
☐ Subject Worksheets <i>(English)</i>			
<i>(Filipino)</i>			
☐ Patient Diary/Alert Card <i>(English)</i>			
<i>(Filipino)</i>			
☐ Questionnaire <i>(English)</i>			
<i>(Filipino)</i>			
☐ Case Report Form (CRF)/e-CRF or Data Collection Form			
☐ Project Summary & Flow Chart of the Protocol			
☐ Material to be used for Recruitment of research participants			
☐ Budget Proposal Form			
☐ IERC Initial Submission Checklist Form			
☐ PFDA Approval			
☐ Curriculum Vitae of Investigator(s)/Proponents			
☐ GCP Training Certificate(s) of Investigator(s)/Proponents			
☐ Attestation(s), if online GCP (NIDA,			
☐ Disclosure of Conflict of Interest Form(s)			
☐ Certificate of Insurance and Insurance Policy			
☐ Updated PRC License of Investigator(s) and Sub-Investigator(s)			
☐ License to Operate to conduct a clinical trial			
Remarks:			
SUBMITTED BY: _____ Date: _____ <i>(Signature over Printed Name)</i>		ISRC/CCT ACKNOWLEDGMENT: _____ Date: _____ <i>(Signature over Printed Name)</i>	
SLMC-IERC Form #02C V05/2024			



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SOP FORM TITLE: Initial Protocol Review Acknowledgment Form	SOP FORM NO.: FORM # 02C

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SOP FORM TITLE: SLMC-IERC Initial Review Form	SOP FORM NO.: FORM # 02D

		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
SLMC-IERC Initial Review Form			
IERC Number:			
Title:			
Please answer the following questions to determine the appropriate type of review:			
		Yes	No
1. Determination if Activity is Research Is the activity a research based on the following criteria? - systematic investigation (including research development, testing and evaluation) - designed to develop or contribute to generalizable knowledge - experiment that involves a test article and one or more human subjects that requires prior submission or for which the results are intended to be submitted later to or held for inspection by the FDA as part of an application for a research or marketing permit. If YES to any of the above, then the study is research. Proceed to Section 2 Determination if Human Research. If not research, then study is exempt from review.			
2. Determination if Human Research Does the research involve human participants based on the following criteria? - Data being obtained is about one or more living individuals - Data collected is through an intervention or interaction with the subject - Identifiable private information is being obtained (includes behavior or medical records review). - involves an individual who is or becomes a participant in research or an investigation If YES to any of the above, then human research. Proceed to Section 3 Determination of Type of Review. If not human, it may be exempt from review.			
3. Determination of Type of Review a. Criteria for Exempt from Review Is the protocol exempt from review based on the following criteria? - neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., systematic and meta-analysis protocols) - case studies or case reports that do not involve the use of articles (e.g., drugs, devices, biologics) that have not been approved for use in humans - does not involve more than minimal risks or harms, such as those that are for: i. institutional quality assurance purposes ii. evaluation of public service programs iii. public health surveillance iv. educational evaluation activities v. consumer acceptability tests - only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met: i. no disclosure of the human participants' responses outside the research; and ii. identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant. - involves the use of publicly available data or information. - retrospective case report or study with no personal identifiers of the patient - database will be used primarily for clinical care or hospital operations purposes If YES , then exempt from review . If not, Proceed to Section 3.b Criteria for Expedited Review.			
SLMC-IERC Form #02D V06/2024		1 2	



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	Yes	No
b. Criteria for Expedited Review Is the protocol for expedited review based on the following criteria? • non-interventional clinical research protocols that entail only a minimal risk to the human participants and to the community • human research participants do not belong to a vulnerable group • clinical research protocols that are retrospective in data collection methodology If YES, protocol is for expedited review . If not, it will require a full board review.		
4. Level of Risk Determination: Choose the appropriate risk level based on the following criteria: High Risk - the study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution. The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation. Moderate Risk – the study risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects. Minimal risk - the study consequences can be dealt with by routine operations; the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.		

Initial Review Summary			
Type of Research			
Sponsor-Initiated Trial (SIT)		Investigator-Initiated Trial (IIT)	
<i>Pharmaceuticals, CROs, AROs</i> ☐ Drug ☐ Phase 1 ☐ Medical device ☐ Phase 2 ☐ Procedure ☐ Phase 3 ☐ Observational ☐ Phase 4 ☐ Others, specify:		<i>For Consultant/Fellow/Resident/Faculty/Personnel/Student</i> ☐ Biomedical Study ☐ Case study/report ☐ Health Operations Research ☐ Systematic review & meta-analysis ☐ Public Health Research ☐ Registry/Databank ☐ Social/Behavioral Research ☐ Others, specify:	
Type of review:	☐ Exempt from review	☐ Expedited review	☐ Full board review
Risk Level:	☐ Minimal risk	☐ Moderate risk	☐ High risk
External/Independent Consultant required?	☐ Yes		☐ No
Remarks:			
Name and signature of SLMC-IERC Reviewer:		Date: (MM/DD/YYYY)	

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SOP FORM TITLE: Ethics Review Form for Protocol	SOP FORM NO.: FORM # 02E



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

ETHICS REVIEW FORM FOR PROTOCOL
☐ Expedited ☐ Full Board

EC Reference No.: Enter Study Reference No	Principal Investigator: Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	Contact Nos. Enter mobile/landline nos.
Title of Protocol: Enter Title	
Type of Protocol: (check appropriate boxes)	
* Sponsor-Initiated Trial (SIT)-Pharmaceuticals, CROs, AROs ☒ Clinical Trial ☒ Drug ☒ Medical device ☒ Procedure ☒ Observational ☒ Others ☒ Phase 1 ☒ Phase 2 ☒ Phase 3 ☒ Phase 4	* Investigator-Initiated Trial (IIT)-Consultant/Fellow/Resident/Faculty/Personnel/Student ☒ Interventional Clinical Research ☒ Drug ☒ Medical device ☒ Procedure ☒ Biomedical (observational, epidemiologic) ☒ Public Health Research ☒ Health Operations Research ☒ Social/Behavioral Research ☒ Prospective Case Study/Report ☒ Registry/Databank ☒ Others
Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO	
Agreement on Confidentiality and Conflict of interest (COI) As a member of the St. Luke's Institutional Ethics Review Committee (IERC), I may be provided with confidential information and documentation (referred to here as "Confidential Information"). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member. Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.	

INSTRUCTIONS for the IERC:
The following is a checklist of ethical issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if compliant with ICH-GCP Standards
- NO, if not compliant, and specify the issue to be addressed in the REMARKS/RECOMMENDATIONS column
- N/A if not applicable.

I. CHECKLIST FOR ETHICAL REVIEW OF PROTOCOL

A. Review of the Protocol	Y	N	N/A	REMARKS/RECOMMENDATIONS
1. Qualified Principal Investigator/Proponent and Research Team (Based on CV, GCP training certificate)				
2. Disclosure of conflict of interest by the Principal investigator/Project Leader				
3. Social and Scientific Value (Will it improve health and well-being or increase knowledge?)				

SLMC-IERC FORM #02E V05/2024 (Protocol)

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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

	Y	N	N/A	REMARKS/RECOMMENDATIONS
4. Scientific Validity - Use of accepted scientific principles and methods, to produce reliable and valid data <i>a. Clear rationale for doing the research</i> <i>b. Adequate literature review, gaps identified</i> <i>c. Clear objectives (SMART) – are they scientific, ethical, feasible?</i> <i>d. Appropriate methodology</i> • Research design (descriptive, experimental, etc.) • Operational definition of terms • Target population and eligibility criteria • Indicators of variables to be used • Relationships between variables that will be explored • Procedures to be performed • Equipment to be used <i>e. Clear and appropriate outcomes</i> <i>f. Adequate and feasible sample size</i> <i>g. Appropriate statistical plan</i> • Quantitative (use of statistical tools and analysis to arrive at generalizable conclusions) • Qualitative (provides in depth insights about specific behavior of social phenomenon)				
B. Review of Ethical Issues (Required)	Y	N	NA	REMARKS/RECOMMENDATIONS
1. Fair selection of subjects <i>(Is selection of subjects not biased so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research?)</i>				
2. Justification for inclusion of vulnerable population <i>such as children, elderly, illiterate, severe physical or mental illness/ condition, prisoners, pregnant women, minority population (migrants, etc.), stigmatized groups (sex workers, drug addicts), deviant behavior, in a dependent relationship with investigator (client or professional relationship, trainees/students/employees)</i>				
3. Justifiable use of a placebo				
4. Standard of care not compromised				
5. Favorable risk-benefit ratio <i>(Are potential risks to the subject proportionate to the benefits to the subject and society? How are risks minimized and benefits maximized? Are AEs/SAEs identified? How will they be managed? Withdrawal criteria is appropriate and adequate?)</i> <i>Possible risks include physical risks (invasive procedures); psychological risks (psychological discomfort answering questions about private behavior, e.g. sex, etc.); economic risks (possible loss of employment); social risks (research about illegal behavior, possible public disclosure, adverse impact on reputation of communities); political risks (possible political exclusion)</i> <i>Possible benefits include direct or indirect benefits to participant (access to drugs, information, etc.), community (access to technology), society (new knowledge and interventions); feedback to participants/community about research findings; provision of medical care; referral to care if not provided in the research</i>				

SLMC-IERC FORM #02E V05/2024 (Protocol)

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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

	Y	N	NA	REMARKS/RECOMMENDATIONS
6. Inclusion of a section on ethical considerations <i>a. Informed consent process, if applicable</i> <i>b. Anticipated risks and discomforts to subjects</i> <i>c. Expected benefits to the subject and to others</i> <i>d. Method/s of dealing with AEs, SAEs, indemnification</i> <i>e. Statement of compliance with the Principles of the Declaration of Helsinki (2013) and ICH-GCP guidelines</i> <i>f. Statement of review and approval of the SL-IERC</i> <i>g. Process of maintaining patient confidentiality and data privacy</i> <i>h. Statement on ensuring integrity of the data, i.e. accuracy, completeness, legibility, originality, timeliness and consistency.</i> <i>i. Manner of disseminating and communicating study results</i> <i>j. Storage, retention and disposal of study-related documents</i>				
Other Comments				

RISK ASSESSMENT: (Check the appropriate box to indicate your risk assessment to participants involved in this clinical trial)

☐ Minimal
 ☐ Moderate
 ☐ High

NOTE:

- A study presents **minimal risk** if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
- A study has **moderate risk** if as a result of research participation, the subjects would be exposed to more than a remote possibility of "substantial or prolonged pain, discomfort, or distress" or "clinically significant deterioration of a medical condition"; subject participant to substantial pain discomfort that is reversible.
- A study with **high risk** to participants is disapproved unless there is a strong justification for the study to be conducted, in which case additional safeguards are recommended.

RECOMMENDED ACTION:

☐ **EXPEDITED REVIEW** (Check the appropriate box to indicate your recommended action on the following):

☐ Approved
☐ With minor revisions
☐ With major revisions

☐ Deferment

☐ For Full Board Review

☐ **FULL BOARD REVIEW** (Check the appropriate box to indicate your recommended action on the following):

☐ Approved
☐ With minor revisions
☐ With major revisions

☐ Deferment

☐ Disapproved

Reviewed by:

 (Name & Signature of Reviewer)

 (Date)

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SOP FORM TITLE: Ethics Review Form for Informed Consent	SOP FORM NO.: FORM # 02F



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

ETHICS REVIEW FORM FOR INFORMED CONSENT

☐ Expedited ☐ Full Board

EC Reference No.: Enter Study Reference No	Principal Investigator: Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	Contact Nos. Enter mobile/landline nos.
Title of Protocol: Enter Title	
Type of Protocol: <i>(check appropriate boxes)</i>	
* Sponsor-Initiated Trial (SIT)-Pharmaceuticals, CROs, AROs * Clinical Trial * Drug * Medical device * Procedure * Observational * Others * Phase 1 * Phase 2 * Phase 3 * Phase 4	* Investigator-Initiated Trial (IIT)-Consultant/fellow/Resident/faculty/Personnel/Student * Interventional Clinical Study * Drug * Medical device * Procedure * Biomedical (observational, epidemiologic) * Public Health Research * Health Operations Research * Social/Behavioral Research * Prospective Case Study/Report * Registry/Databank * Others _____
Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO	
Agreement on Confidentiality and Conflict of interest (COI) <i>As a member of the St. Luke's Institutional Ethics Review Committee (IERC), I may be provided with confidential information and documentation (referred to here as "Confidential Information"). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member.</i> <i>Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.</i>	

INSTRUCTIONS for the IERC:
 The following is a checklist of ethical issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if compliant with ICH-GCP Standards
- NO, if not compliant, and specify the issue to be addressed in the REMARKS/RECOMMENDATIONS column
- N/A if not applicable.

PARTICULARS	Y	N	NA	REMARKS/RECOMMENDATIONS
1. Appropriate Type of Consent Form (i.e. ICF for Clinical Studies/Assent/ Legally Acceptable Representative)				
2. Following items are included in the Informed Consent Form:	Y	N	NA	REMARKS/RECOMMENDATIONS
a. Name of Principal Investigator, Site of Study, Sponsor				
b. An explanation that the study involves research				
c. Title of the study				

SLMC-IERC FORM # 02F V05/2024 (ICF)

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SOP FORM TITLE: Ethics Review Form for Informed Consent	SOP FORM NO.: FORM # 02F

		INSTITUTIONAL ETHICS REVIEW COMMITTEE		
	Y	N	NA	REMARKS/RECOMMENDATIONS
d. Purpose of the study				
e. Type of research intervention				
f. Nature of participation (treatment or control)				
g. Possibility for random allocation				
h. Information on the trial drug				
i. Expected duration of participation				
j. Responsibilities of the participant				
3. The consent form is written in a language that a layman can understand.				
4. The procedure written in the ICF is consistent with the protocol.				
5. The participant is informed of the following:	Y	N	NA	REMARKS/RECOMMENDATIONS
a. Informed Consent will be obtained				
b. Explanation of anticipated risks and discomforts of each procedure/drug				
c. Possible benefits of each procedure/drug				
d. Possible adverse effects of each procedure and/or drug				
6. There is a statement about reimbursement for study/ trial-related expenses.				

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Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Ethics Review Form for Informed Consent	SOP FORM NO.: FORM # 02F

St. Luke's Medical Center <i>We love life.</i>		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
	Y	N	NA
7. There is a statement about responsibility for medical treatments in case of injury during the study.			
8. There is a provision for free choice of contraception.			
9. Time is given for participant to consider whether to participate in the study or not.			
10. There is consideration of the following ethical issues:	Y	N	NA
a. Confidentiality and data privacy			
b. Alternative treatments			
c. Voluntary participation			
d. Right to withdraw anytime without prejudice to the appropriate medical care			
e. Right to know results of tests			
f. Timely release of new information that may affect his willingness to continue his participation in the trial			
g. Statement about what will be done with left-over specimens			
11. The name and signature of the following are included:	Y	N	NA
a. Person getting informed consent			
b. Participant			
c. Witnesses			
d. Representative of participants who are incapacitated			
e. Parent or Guardian (for minors)			
12. The following information are included in the ICF:	Y	N	NA
a. Name and contact number of the PI/Study Coordinator			

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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

	Y	N	NA	REMARKS/RECOMMENDATIONS
b. Name and contact number of the Ethics Review Committee (ERC) Chair				
13. Translation (not necessarily literal) of the ICF from English to Filipino (or other language) is accurate and acceptable.				
14. Indemnity insurance is adequate.				
15. Study advertisements, brochures and patient recruitment materials are appropriate.				
Other comments				

RISK ASSESSMENT: (Check the appropriate box to indicate your risk assessment to participants involved in this clinical trial)

☐ Minimal
 ☐ Moderate
 ☐ High

NOTE:

- A study presents **minimal risk** if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
- A study has **moderate risk** if as a result of research participation, the subjects would be exposed to more than a remote possibility of "substantial or prolonged pain, discomfort, or distress" or "clinically significant deterioration of a medical condition"; subject participant to substantial pain discomfort that is reversible
- A study with **high risk** to participants is disapproved unless there is a strong justification for the study to be conducted, in which case additional safeguards are recommended.

RECOMMENDED ACTION:

☐ **EXPEDITED REVIEW** (Check the appropriate box to indicate your recommended action on the following):

☐ Approved
 ☐ Deferment

☐ With minor revisions
☐ With major revisions

☐ **FULL BOARD REVIEW** (Check the appropriate box to indicate your recommended action on the following):

☐ Approved
 ☐ Deferment
 ☐ Disapproved

☐ With minor revisions
☐ With major revisions

Reviewed by:

 (Name & Signature of Reviewer)

 (Date)

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Ethics Review Form for External/Independent Consultant	SOP FORM NO.: FORM # 02G



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

ETHICS REVIEW FORM
(FOR EXTERNAL/INDEPENDENT CONSULTANT)

EC Reference No.: Enter Study Reference No	Principal Investigator: Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	Contact Nos. Enter mobile/landline nos.
Title of Protocol: Enter Title	
Type of Protocol:	
* Sponsor-Initiated Trial - Pharmaceuticals, CROs, AROs	* Investigator-Initiated Trial - Consultant/Fellow/Resident/Faculty/Personnel/Student
Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO	

INSTRUCTIONS: The following is a list of questions/issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with ICH-GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if appropriate, adequate, and compliant with ICH-GCP Standards
- NO, if neither appropriate, adequate nor compliant, and specify the issue(s) to be addressed in the REMARKS/RECOMMENDATIONS column.

Methodology (Are the following clearly stated/described and appropriate?)	Y	N	REMARKS/RECOMMENDATIONS
1. Qualified Principal Investigator/Proponent and Research Team (Based on CV, GCP training certificate)			
2. Social and Scientific Value (Will it improve health and well-being or increase knowledge?)			
3. Scientific Validity - Use of accepted scientific principles and methods, to produce reliable and valid data a. Clear rationale for doing the research b. Adequate literature review, gaps identified c. Clear objectives (SMART) – are they scientific, ethical, feasible? d. Appropriate methodology • Research design (descriptive, experimental, etc.) • Operational definition of terms • Target population and eligibility criteria • Indicators of variables to be used • Relationships between variables that will be explored • Procedures to be performed • Equipment to be used e. Clear and appropriate outcomes f. Adequate and feasible sample size g. Appropriate statistical plan • Quantitative (use of statistical tools and analysis to arrive at generalizable conclusions) • Qualitative (provides in depth insights about specific behavior of social phenomenon)			

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		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
Methodology (Are the following clearly stated/described and appropriate?)	Y	N	REMARKS/RECOMMENDATIONS
4. Vulnerability of Patient Population (e.g. children, elderly, illiterate, severe physical or mental illness/ condition, prisoners, pregnant women, minority population (migrants, etc.), stigmatized groups (sex workers, drug addicts), deviant behavior, in a dependent relationship with investigator (client or professional relationship, trainees/students/employees)			
5. Risks and Benefits (Are risks minimized and benefits maximized?)			
6. Medical Care (Is standard of care compromised?)			
7. Other Comments			
Reviewed by: Printed Name and Signature		Date:	

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Ethical Clearance	SOP FORM NO.: FORM # 03A

 St. Luke's Medical Center <i>We love life.</i>		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
ETHICAL CLEARANCE			
EC Reference No.:		Protocol Title/No:	
Principal Investigator/Institute:		Address:	Date of Approval:
Email Address & Contact No.:	Sponsor/CRO:		Valid until:
This clinical trial has been approved by the SL-IERC to be of <Enter Risk Level> risk. The frequency of Continuing Review Reporting shall be <Enter Frequency>: • <Enter Due Date of Submissions>			
Note: Submit Continuing Review Report one (1) month before the due date above. No submission means cancellation of ethical clearance.			
The following documents were reviewed and approved for use in this study: Protocol <Write title, version no., date> Informed Consent Forms <Write version no., date> Case Report Forms or Data Collection Forms (if applicable) <Write version no.> Advertisement materials (if applicable) <Write date> Patient's diary (if applicable) Other Study Materials <Write version no., date> Below are additional study documents included in the review as basis for the approval of the study. Investigator's Brochure (Write version no., date) CV and GCP of Study Team ----- Nothing follows -----			
<Enter Name> Chair, Institutional Ethics Review Committee			
Note: 1. This Ethical Clearance carries with it Principal Investigator's commitment to comply with international and national guidelines on Good Clinical Practice. Please see attached for strict compliance. 2. The Principal Investigator can commence this study upon approval of the Clinical Trial Agreement or Memorandum of Agreement.			
♦ (This Committee is recognized by SIDCER Strategic Initiative for Developing Capacity in Ethical Review) and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) and accredited by PHREB (Philippine Health Research Ethics Board). ♦ The Committee is fully compliant with the regulations as they relate to ethics committee and the conditions and principles of Good Clinical Practice.			

SLMC-IERC FORM # 03A V05/2024

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SOP FORM TITLE: Ethical Clearance	SOP FORM NO.: FORM # 03A

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SOP FORM TITLE: Response to Notice of Action Evaluation Form	SOP FORM NO.: FORM # 03B

RESPONSE TO NOTICE OF ACTION
(EVALUATION FORM)

EC Reference #:

Protocol Title:

Comments/Suggestions:

SL-IERC Action:

☐ Approved
 ☐ For Further Clarification
 ☐ For Full-board
 ☐ For further Evaluation _____

Reviewed by:

Name & Signature

Date

SLMC-IERC FORM # 03B V05/2024



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Response to Notice of Action Evaluation Form	SOP FORM NO.: FORM # 03B

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SOP FORM TITLE: Continuing Review/Progress Report Form	SOP FORM NO.: FORM # 04A



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

CONTINUING REVIEW/ PROGRESS REPORT FORM

EC Reference No.: SL- _____ Protocol No.: _____ Principal Investigator: _____ Institute/Department: _____ Sponsor/CRO: _____ Protocol Title: _____ _____ _____ _____	For SLMC-IERC use: ☐ Sponsor-initiated Trial ☐ Investigator-initiated Trial Type of Initial Review: ☐ Full Board ☐ Expedited IERC Ethical Clearance Date: _____ Ethical Clearance validity date: _____ Continuing Review Interval: ☐ Annual ☐ Semi-Annual ☐ Quarterly Continuing Review Date: _____

Use this form if you are requesting approval for continuation of this study, i.e. if you are still actively recruiting participants or continuing visits; collecting data and analysis; or writing manuscripts for publications. If all data collection and participant follow-up has ended and the study is either completed or cancelled, attach an accomplished Final Report Form.

RESEARCH TEAM			
Name	Role (PI, Co-I, Research Nurse etc.)	Responsibilities (* indicate numbers from the study tasks listed below)	Date of GCP Training

***Study Tasks**
 1- Protocol Development 4 – Obtain Informed Consent 7 – Data Entry
 2 – Study protocol assessments/procedures 5- Chart Review 8 – Data Analysis
 3- Participant recruitment 6- Data Collection 9 – Protocol Amendments

DETAILS OF THE STUDY	
Section 1: STATUS OF STUDY (What is the current status of this study? Check all that apply)	
1. ☐ Study not started (proceed to Sections: 5,6 and 9) Explain* _____	
2. ☐ Open Study ☐ Data Collection (Retrospective: Chart Review) ☐ Recruiting (The study is currently recruiting participants) ☐ Not yet recruiting (The study has not started recruiting participants)	
3. ☐ Closed Study ☐ Active, Not recruiting (The study is ongoing, that is participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled) ☐ Completed (The study has ended normally and participants are no longer being examined or treated, that is, the "last subject, last visit" has occurred). ☐ Terminated (the study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated). ☐ Suspended (The study has stopped recruiting or enrolling participants early, but may start again). ☐ Withdrawn (The study stopped recruiting or enrolling its first participant).	

SLMC-IERC Form # 04A V07/2024

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SOP FORM TITLE: Continuing Review/Progress Report Form	SOP FORM NO.: FORM # 04A

Enrolling by invitation (A study that selects its participants from a population, or group of people, decided on in advance by the researchers. These studies are not open to everyone who meets the eligibility criteria, but only to people in that particular population, who are specifically invited to participate).

4. Data Analysis
 5. Manuscript/Publication Phase
 6. For study close-out Expected Date: _____
 * If necessary, use additional sheets

Section 2: STUDY PARTICIPANTS

1. Enrollment Status
 Number of participants required for this site
 No enrollment to date (proceed to Sections 3 nos. 1, 5,6 and 9)

2. Screening
 Number of participants in the screening stage

3. Enrolled participants
 Number of consented participants enrolled
 Number of participants still on study drug/undergoing study procedures (i.e. lab tests, questionnaires)
 Number of participants completed taking study drug/study procedure but currently in follow-up

4. Participants Outcomes
 Number of participants who have been withdrawn/terminated from the study (due to withdrawal of consent, loss to follow-up, death)
 Number of participants who have completed the study

5. Biological Samples (if applicable)
 Number of biological samples utilized for a retrospective study data

Note: For chart review/registry research state number of charts under enrolled field.
 State reason if difficulty is encountered in recruiting participants. _____

Section 3: INFORMED CONSENT PROCESS

1. Number of participants who signed Informed Consent Form (ICF) but failed screening.
 2. Number of consented participants who discontinued before treatment/study procedures began.
 3. Number of consented subjects who discontinued due to occurrence of SAE or AE
 4. Number of consented participants who discontinued before trial completion.
 Reasons: _____

5. Number of subjects enrolled but failed to sign consent prior to performance of any procedures
 Reasons: _____

6. List the consent form(s) currently in use (e.g. main, genomics, etc.)

Consent Form	Version / Date	Date approved by IERC

Section 4: SAFETY REPORTING

1. Serious Adverse Event(SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Information Summary (site only) N/A
 Number of site SAEs
 Number of site SUSARs

2. Summary of all ON SITE SAEs/SUSARs since initial approval*

Participant Study Number	Date of Onset	Description of SAE/SUSAR	Date reported to IERC	Study Drug Relationship (Yes, No, N/A)	Outcome

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* If necessary use additional sheets			
3. Has the study been stopped, put on hold or recruitment put on hold at any site for any reason?*			
___ Yes ___ No ___ N/A			
*If YES, in additional sheet, provide details including dates.			
Section 5: PROTOCOL AMENDMENTS ___ N/A			
Detail all protocol amendments since initial approval, version number and date and date of IERC approval.			
Date amendment submitted to IERC	Amendment Version Number (or description)	Amendment version date	Date approved by IERC
Section 6: NEW INFORMATION			
Is there any new information in the literature, interim findings or preliminary results that would change the rationale, procedures, study design and/or risk benefit profile of this study since the last review? ___ Yes ___ No			
If YES, in additional sheet, please describe.			
Section 7: PROTOCOL VIOLATIONS/DEVIATIONS			
Is there any protocol violation that occurred since the last IERC review? ___ Yes ___ No			
If YES, in additional sheet, please attach a copy(s). (Any protocol violation should have been reported as soon as PI have been notified of its occurrence. If not, please explain why IERC was not informed immediately.)*			
Characterization (Refer to PD/Violation Form)	Description	Date of awareness	Corrective Action
*If necessary use additional sheets			
Section 8: STUDY MONITORING VISITS			
1. Has this study been monitored by the sponsor (CRM/CRA) within the last IERC review? ___ Yes ___ No			
If yes, state:			
Date(s) of Monitoring: _____			
Type of Monitoring Visit: _____			
2. Have there been any issues/findings during the monitoring visit? ___ Yes ___ No			
If yes, please attach copy(s) of the Monitoring Report/Follow-up Letter.			
Section 9: AUDIT			
1. Has this study been audited by any local or foreign regulatory authorities within the last IERC review? ___ Yes ___ No			
If yes, state:			
Date of audit: _____			
Regulatory authority: _____			
2. Have there been any issues/findings during the audit? ___ Yes ___ No			
If yes, please attach copies of the Established Inspection Report (EIR).			
Section 10: ATTACHMENTS			
Kindly submit copy of the latest Good Clinical Practice Certificate, Curriculum Vitae and Disclosure of Conflict of Interest (signed and dated) of all the study team members (applies on anniversary dates only).			



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Submitted by: <i>(PI Name and Signature)</i> <i>(Date)</i>		IERC Acknowledgment: <i>(Secretariat Name and Signature)</i> <i>(Date)</i>	
EC Reference No.:	Name of PI/Project Leader:	Institute/Department:	
Primary Reviewer:			
☐ For Approval of Renewal ☐ Request further information ☐ For Termination		☐ For approval of study continuation ☐ Deferment of Action ☐ For Suspension	
Recommended Action (Frequency of Report): ___ ANNUAL ___ SEMI ___ QUARTERLY			
REMARKS (If any): _____ _____ _____ _____			
Member in Charge:			
☐ For Approval of Renewal ☐ Request further information ☐ For Termination		☐ For approval of study continuation ☐ Deferment of Action ☐ For Suspension	
Recommended Action (Frequency of Report): ___ ANNUAL ___ SEMI ___ QUARTERLY			
REMARKS (If any): _____ _____ _____ _____			
Reviewed by: <i>(Signature over printed name)</i>		Date:	
SL-IERC ACTION:			
☐ Approved for Renewal ☐ Approved for Continuation (___ ANNUAL ___ SEMI ___ QUARTERLY) ☐ Request further information ☐ Deferment of Action NOA sent out date : _____ Response to NOA receipt date : _____ ☐ For Termination ☐ For Suspension		Noted by: <i>(IERC Chair Name and Signature)</i> <i>(Date)</i>	



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Final Report Form	SOP FORM NO.: FORM # 04B

		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
FINAL REPORT			
EC Reference No.: CT or SL -		Protocol No.:	
Principal Investigator:		For SLMC-IERC use:	
Institute/Department/Sponsor/CRO:		☐ Sponsor-initiated Trial ☐ Investigator-initiated Trial	
Protocol Title:		Type of Initial Review:	
		☐ Full Board ☐ Expedited	
Study Status:		IERC Ethical Clearance Date:	
☐ Final report (Completed) ☐ Termination		Study Ended/Close-out Date:	
REASON FOR TERMINATION (please check all that apply)			
☐ Insufficient enrolment or recruitment challenges ☐ Safety concerns or adverse events ☐ Lack of funding or resources ☐ Changes in protocols due to external factors ☐ Ineffectiveness of the intervention ☐ Other (please specify):			
Section 1: STUDY PARTICIPANTS (Write N/A if not applicable)			
1. _____ Number of participants required for this site 2. _____ Number of consented, chart Review or Registry participants enrolled 3. _____ Number of participants who have been withdrawn/terminated from the study due to withdrawal of consent, loss to follow-up, death, etc. 4. _____ Number of biological samples utilized for a retrospective study data			
Section 2: DEVIATIONS FROM THE PROTOCOL			
Were there any deviations from the protocol? ☐ No ☐ Yes. If yes, please specify and provide reason for deviation.			
Section 3: ISSUES/PROBLEMS			
1. Were there any unanticipated problems involving risks to subjects or others at your site that have not been previously reported to IERC? ☐ N/A ☐ No ☐ Yes. If Yes, kindly attach a report to this form.			
2. Were there other issues or problems encountered? ☐ No ☐ Yes. If Yes, kindly described.			
Section 4: FINDINGS AND CONCLUSION			
Summary of findings:			
Conclusion:			
Section 5: DISSEMINATION (Publication / Presentation)			
Actions for dissemination of study results:			
Submitted by:		IERC Acknowledgment:	
_____ (PI Name and Signature) (Date)		_____ (Name and Signature of IERC Secretariat) (Date)	
Primary Reviewer:		Reviewed by:	
☐ For closure of file and archiving ☐ Full board Review ☐ Request further information ☐ Recommend further action Remarks: _____		_____ (Name and Signature of Reviewer) (Date)	



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SOP FORM TITLE: Final Report Form	SOP FORM NO.: FORM # 04B

SL-IERC Member-in-Charge:	
☐ For closure of file and archiving ☐ Full board Review ☐ Request further information ☐ Recommend further action Remarks: _____ _____	Reviewed by: _____ (Name and Signature of Reviewer) (Date)
SL-IERC ACTION:	
☐ For closure of file and archiving ☐ Request further information ☐ Recommend further action NOA sent out date: _____	Noted by: _____ (Name and Signature of IERC Chair) (Date)



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Termination Report Form	SOP FORM NO.: FORM # 04C

		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
TERMINATION REPORT			
EC Reference No.: CT or SL -		Protocol No.:	
Principal Investigator:		For SLMC-IERC use:	
Institute/Department:		☐ Sponsor-initiated Trial ☐ Investigator-initiated Trial	
Sponsor/CRO/ Sponsor Contact Person:		Type of Initial Review:	
Protocol Title:		☐ Full Board ☐ Expedited	
Briefly describe the reason(s) for terminating the project before its planned completion.		IERC Ethical Clearance Date:	
		Original Planned End Date:	
REASON FOR TERMINATION (please check all that apply. Attach detailed explanation for each reason.) ☐ Insufficient enrolment or recruitment challenges ☐ Safety concerns or adverse events ☐ Lack of funding or resources ☐ Changes in protocols due to external factors ☐ Ineffectiveness of the intervention ☐ Other (please specify): _____			
Section 1: PROJECT STATUS AT TERMINATION (Describe the status of the project at the time of termination. This may include:)			
1. _____ Number of participants enrolled (if applicable) 2. _____ Amount of data collected (if applicable) 3. _____ Progress made towards achieving project objectives (if any) 4. _____ Any completed phases or milestones			
Section 2: PATIENT SAFETY MANAGEMENT PLAN (Describe the plan for managing ensure patient safety during and after the study termination. This section is crucial if termination was related to safety issues. This may include:			
1. Actions Taken to Protect Participants: _____ 2. Follow-Up Procedures for Participants: _____ 3. Notification of Termination to Participants: _____ 4. Handling of Adverse Events: _____ 5. Review of Safety Data: _____			
Section 2: DATA MANAGEMENT PLAN (Describe the plan for managing any data collected up to the point of termination. This may include:			
1. Data storage procedures _____ 2. Data security measures _____ 3. Data retention period _____ 4. Data destruction procedures (if applicable) _____ 5. Plans for data sharing or publication (if applicable) _____			
Submitted by:		IERC Acknowledgment:	
_____ (PI Name and Signature) (Date)		_____ (Name and Signature of IERC Secretariat) (Date)	
SL-IERC Primary Reviewer:		Reviewed by:	
☐ For closure of file and archiving ☐ Full board Review ☐ Request further information ☐ Recommend further action Remarks: _____		_____ (Name and Signature of Reviewer) (Date)	
SL-IERC Member-in-Charge:		Reviewed by:	
☐ For closure of file and archiving ☐ Full board Review ☐ Request further information ☐ Recommend further action Remarks: _____		_____ (Name and Signature of Reviewer) (Date)	
SL-IERC ACTION:		Noted by:	
☐ For closure of file and archiving ☐ Request further information ☐ Recommend further action NOA sent out date: _____		_____ (Name and Signature of IERC Chair) (Date)	



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SOP FORM TITLE: Termination Report Form	SOP FORM NO.: FORM # 04C

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Renewal Ethical Clearance	SOP FORM NO.: FORM # 04D



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Medical Center
We love life.

**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

RENEWAL OF ETHICAL CLEARANCE

EC Reference No.:	Protocol Title/No:	
Principal Investigator/Institute:	Address:	Date of Approval:
Email Address & Contact No.:	Sponsor/CRO:	Valid until:

The following documents were reviewed and approved for use in this study:

Protocol <Write title, version no., date>
Informed Consent Forms <Write version no., date>
Case Report Forms or Data Collection Forms (if applicable) <Write version no.>
Advertisement materials (if applicable) <Write date>
Patient's diary (if applicable)
Other Study Materials <Write version no., date>

Below are additional study documents included in the review as basis for the approval of the study.
Investigator's Brochure (Write version no., date)
CV and GCP of Study Team

----- Nothing follows -----

<Enter Name>
 Chair, Institutional Ethics Review Committee

Note:
 This Ethical Clearance carries with it Principal Investigator's commitment to comply with international and national guidelines on Good Clinical Practice. Please see attached for strict compliance.

★ (This Committee is recognized by SIDCER Strategic Initiative for Developing Capacity in Ethical Review) and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) and accredited by PHREB (Philippine Health Research Ethics Board).

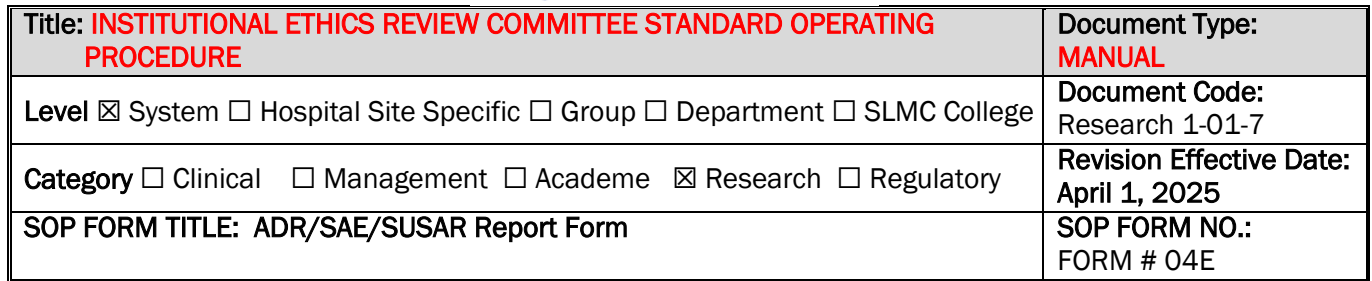
★ The Committee is fully compliant with the regulations as they relate to ethics committee and the conditions and principles of Good Clinical Practice.

SLMC-IERC FORM # 04D V05/2024 (Renewal)



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Renewal Ethical Clearance	SOP FORM NO.: FORM # 04D

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: ADR/SAE/SUSAR Report Form	SOP FORM NO.: FORM # 04E

For IERC use only

ADR/SAE/SUSAR ASSESSMENT FORM

SLMC-IERC Primary Reviewer (Comments/Recommendations):

SLMC-IERC Primary Reviewer:
☐ No further action
☐ Request further information
☐ Changes to the research protocol to eliminate apparent immediate hazards to subjects.
☐ Modification of inclusion or exclusion criteria to mitigate the newly identified risks
☐ Implementation of additional procedures for monitoring subjects.
☐ Suspension of enrolment of new subjects
☐ Suspension of research procedures in currently enrolled subjects
☐ Modification of informed consent documents to include a description of newly recognized risks
☐ Provision of additional information about newly recognized risks to previously enrolled subjects

Reviewed by: _____
(Signature over Printed Name)

Date: _____

SLMC-IERC Member-Pharmacologist (Comments/Recommendations):

SLMC-IERC Member-Pharmacologist:
☐ No further action
☐ Request further information
☐ Changes to the research protocol to eliminate apparent immediate hazards to subjects.
☐ Modification of inclusion or exclusion criteria to mitigate the newly identified risks
☐ Implementation of additional procedures for monitoring subjects.
☐ Suspension of enrolment of new subjects
☐ Suspension of research procedures in currently enrolled subjects
☐ Modification of informed consent documents to include a description of newly recognized risks
☐ Provision of additional information about newly recognized risks to previously enrolled subjects

Reviewed by: _____
(Signature over Printed Name)

Date: _____

SLMC-IERC Form # 04E V07/2024

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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SOP FORM TITLE: ADR/SAE/SUSAR Report Form	SOP FORM NO.: FORM # 04E

SLMC-IERC Member-in-Charge (Comments/Recommendations):	
SLMC-IERC Member-in-Charge Action: ☐ No further action ☐ Request further information ☐ Changes to the research protocol to eliminate apparent immediate hazards to subjects. ☐ Modification of inclusion or exclusion criteria to mitigate the newly identified risks ☐ Implementation of additional procedures for monitoring subjects. ☐ Suspension of enrolment of new subjects ☐ Suspension of research procedures in currently enrolled subjects ☐ Modification of informed consent documents to include a description of newly recognized risks ☐ Provision of additional information about newly recognized risks to previously enrolled subjects	
Reviewed by: _____ (Signature over Printed Name)	Date: _____

SLMC-IERC Form # 04E V07/2024
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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Protocol Deviation/Violation Form	SOP FORM NO.: FORM # 04F

		INSTITUTIONAL ETHICS REVIEW COMMITTEE									
<u>PROTOCOL DEVIATION/VIOLATION FORM</u>											
EC Reference No.: <u>SL-</u>		Protocol No: _____									
Principal Investigator: _____		Inst./Dept.: _____									
Protocol Title: _____											
Protocol Violation: means an accidental or unintentional change to, or non-compliance with the SLMC-IERC approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) without prior sponsor and SLMC-IERC approval. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data. Examples of protocol violations: - Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form) - Loss of laptop computer that contained identifiable, private information about subjects - Accidental distribution of incorrect study medication or dose - Not following inclusion/exclusion criteria - Falsifying data or research records. - Failing to follow proper data collection or storage procedures. <i>Note: * as described in IERC SOP 4.3: If there is lapse in IRB approval this report should also be submitted.</i>											
Protocol Deviation: means a minor or administrative departure from the SLMC-IERC-approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior Sponsor and SLMC-IERC approval. It is an accidental or unintentional change to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of the Principal Investigator or the Clinical Trial staff. Examples of a deviation include: - A rescheduled study visit - Failure to collect an ancillary self-report questionnaire - Subject's refusal to complete scheduled research activities											
I. Date of occurrence:		Date of awareness:									
II. Characterization:											
The deviation/violation involves: <table border="0"> <tr> <td>☐ Enrollment process (inclusion/exclusion criteria etc.)</td> <td>☐ Other protocol activities (research activities, data analysis, reporting, etc.)</td> </tr> <tr> <td>☐ Consent Process (oral/written)</td> <td>☐ Complaint from research subject</td> </tr> <tr> <td>☐ Drug/Device Administration (dosage, schedule, route of administration, formulation, etc.)</td> <td>☐ Audit finding that requires corrective action</td> </tr> <tr> <td></td> <td>☐ Other: _____</td> </tr> </table>				☐ Enrollment process (inclusion/exclusion criteria etc.)	☐ Other protocol activities (research activities, data analysis, reporting, etc.)	☐ Consent Process (oral/written)	☐ Complaint from research subject	☐ Drug/Device Administration (dosage, schedule, route of administration, formulation, etc.)	☐ Audit finding that requires corrective action		☐ Other: _____
☐ Enrollment process (inclusion/exclusion criteria etc.)	☐ Other protocol activities (research activities, data analysis, reporting, etc.)										
☐ Consent Process (oral/written)	☐ Complaint from research subject										
☐ Drug/Device Administration (dosage, schedule, route of administration, formulation, etc.)	☐ Audit finding that requires corrective action										
	☐ Other: _____										
III. Description											
1) Participant ID (if applicable; if more than one participant is involved list all the IDs)											
2) If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse (use additional sheet of paper(s); if not proceed to no.2)											
SLMC-IERC Form #04F V07/2024											



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3) Describe in detail specific violation/deviation: (use additional sheet of paper(s) if needed)	
4) Explain how/why the deviation occurred. (use additional sheet of paper(s) if needed)	
5) Describe how the deviation/violation affected the following:	
a. Risk/benefit ratio for the subject: Was there a change?	Yes, why? No, why?
b. Integrity of the research data: Was it compromised?	Yes, why? No, why?
c. Is the subject willing to continue study participation?	Yes No, why?
6) Does this protocol deviation/violation require revision of the protocol and/or consent form?	
☐ Yes (If YES, please submit a completed amendment form and revised documents with changes marked) ☐ No	
7) Please describe: (i) corrective actions, if applicable, for the deviation/violation; and (ii) a plan for preventing the recurrence of the deviation/violation:	
By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that, upon receipt of the SL-IERC's review, I will fully and immediately implement any corrective actions required by the SL-IERC. Signature of PI _____ Date _____ Signature of co-PI (if applicable) _____ Date _____ SLMC-IERC Form #04F V05/2024	



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SOP FORM TITLE: Protocol Deviation/Violation Form	SOP FORM NO.: FORM # 04F

PROTOCOL DEVIATION/VIOLATION ASSESSMENT FORM

For IERC use only

1. SLMC-IERC Primary Reviewer

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

☐ No further action is required.

☐ The corrective action described in this form is acceptable and must be implemented. PI must issue a statement to the SLMC-IERC that he/she has implemented the corrective action plan as described.

☐ PI must submit an interim report to the SLMC-IERC on _____ describing his/her progress in implementing the corrective action described below.

☐ The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.

☐ Other: _____

COMMENTS:

(Signature above printed name) _____ Date _____

2. SLMC-IERC Member-in-Charge

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

☐ No further action is required.

☐ The corrective action described in this form is acceptable and must be implemented. PI must issue a statement to the SLMC-IERC that he/she has implemented the corrective action plan as described.

☐ PI must submit an interim report to the SLMC-IERC on _____ describing his/her progress in implementing the corrective action described below.

☐ The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.

☐ Other: _____

COMMENTS:

(Signature above printed name) _____ Date _____

SLMC-IERC Form #04F V05/2024



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SOP FORM TITLE: Protocol Deviation/Violation Form	SOP FORM NO.: FORM # 04F

3. SLMC-IERC Action on Protocol deviation/violation

☐ No Further action required

☐ Requires further information

NOA Release Date : _____

Response to NOA Receipt Date : _____

☐ To submit reports that corrective actions have been implemented

NOA Release Date : _____

Response to NOA Receipt Date : _____

☐ Place restrictions on the study team personnel that may have been responsible for the deviation/violation

☐ Audit Principal Investigator/Project Leader's site by an SLMC-IERC Member or by a Clinical Research Monitor

☐ Increase the frequency of the continuing review period for the study

☐ Suspend or terminate the study or any portion of that study which may increase risk to participants or others.

☐ For review according to policy required

Other: _____

Comments:

Noted by SLMC-IERC Chair:

(Signature above printed name)

Date

SLMC-IERC Form #04F V05/2024



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Protocol Amendment Form	SOP FORM NO.: FORM # 04G

St. Luke's Medical Center We love life.	INSTITUTIONAL ETHICS REVIEW COMMITTEE												
PROTOCOL AMENDMENT FORM													
EC Reference #: <u>SL-</u> _____ Protocol No. _____ Principal Investigator: _____ Inst./Dept.: _____ Ethical Clearance validity date: _____ Sponsor/CRO: _____ Protocol Title: _____													
Note: Kindly check below the document(s) for review. Submit 2 copies of the new version and supporting documents (if applicable), completed Protocol Amendment form and Summary of the revisions. One copy of the new version must indicate the track changes, new text is shown in red font color and bold type; deleted text is shown in red font color with a ~~strike through~~. The other copy of the new version must be the clean copy of the document amended.													
☐ Protocol ☐ Major (e.g. Study design, objective of study, procedure) Does this have significant impact on: ☐ the safety or physical or mental integrity of the subjects, or ☐ the scientific value of the trial, or ☐ the conduct or management of the trial, or ☐ the quality or safety of any IND used in the trial. ☐ Minor (e.g. administrative changes, change of address, grammatical corrections) New version no. & date: _____													
☐ Informed Consent Form ☐ Major (additional risks to the subjects e.g. updates on side effects of study drug) ☐ Minor (administrative changes, change of address, grammatical corrections) New version no. & date: _____													
☐ Change in Investigator/Co-investigator/ member of Study team (Pls. complete information below) ☐ Addition (Kindly provide copy of individual's Curriculum vitae. New members of the study team must be ICH-GCP certified) <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">Name</td> <td style="width: 50%; text-align: center;">Position</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> </table> ☐ Deletion <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">Name</td> <td style="width: 50%; text-align: center;">Position</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> </table>		Name	Position	_____	_____	_____	_____	Name	Position	_____	_____	_____	_____
Name	Position												
_____	_____												
_____	_____												
Name	Position												
_____	_____												
_____	_____												
☐ Other Study Related Materials: Please Specify (Kindly indicate type of document with version date and no.) _____													
Submitted by: _____ (Name and signature of Principal Investigator) _____ Date	Received by: (SLMC-IERC use only) _____ (Name and signature) _____ Date												
SLMC-IERC Form # 04G V07/2024													



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Protocol Amendment Form	SOP FORM NO.: FORM # 04G

1. Comments/Suggestions of SL-IERC Primary Reviewer:	
Does this have significant impact on: (Pls. check all that apply) ☐ the safety or physical or mental integrity of the subjects, or ☐ the scientific value of the trial, or ☐ the conduct or management of the trial, or ☐ the quality or safety of any IND used in the trial. COMMENTS:	
Does the proposed changes/amendments affect the risk-benefit ratio of the study? (If yes, please explain)	
Recommendation:	
Protocol:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Informed Consent Forms:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Study Related Materials:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Name & Signature of SL-IERC Member:	Date:

SLMC-IERC Form # 04G V07/2024



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SOP FORM TITLE: Protocol Amendment Form	SOP FORM NO.: FORM # 04G

2. Comments/Suggestions of the Member-in-Charge on Protocol Amendments:	
Does this have significant impact on: (Pls. check all that apply) ☐ the safety or physical or mental integrity of the subjects, or ☐ the scientific value of the trial, or ☐ the conduct or management of the trial, or ☐ the quality or safety of any IND used in the trial. COMMENTS:	
Does the proposed changes/amendments affect the risk-benefit ratio of the study? (If yes, please explain)	
Recommendation:	
Protocol:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Informed Consent Forms:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Study Related Materials:	☐ Approved ☐ For further Clarification ☐ Suggest modifications ☐ For Full Board
Name & Signature of Member-in-Charge on Protocol Amendments:	Date:
SLMC-IERC Action: ☐ Approved ☐ For further Clarification ☐ For Acknowledgment	
Noted by:	(If applicable) NOA release date: _____ Response to NOA receive date: _____
SLMC-IERC Chair Name & Signature _____	Date _____

SLMC-IERC Form # 04G V07/2024



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Clinical Research/Site Monitoring Form	SOP FORM NO.: FORM # 04H



Research and Biotechnology Group
 OFFICE OF RESEARCH INTEGRITY



CLINICAL RESEARCH/SITE MONITORING FORM

EC Reference No. _____
 Investigator/Project Leader _____
 Project Coordinator _____
 Institute/Department _____
 Protocol Title _____

Monitoring Date _____
 IERC Clearance Date _____
 Reporting Frequency _____
 Status of the Study _____

PATIENT RECRUITMENT SUMMARY	NO.	REMARKS
1. Total no. of required subjects		
2. Total no. of screened subjects		
3. Total no. of enrolled subjects		
4. Total no. of screening failure		
5. Total no. of signed ICF		
6. Total no. of drop-outs		
7. Total no. of subjects withdrawn		
8. Total no. of subjects completed		

Performance Evaluation: N/A=Not applicable; 0=Not met; 1=Partially met; 2=met

ITEMS	Rate				RECOMMENDATIONS/REMARKS
	N/A	0	1	2	
I. SOURCE DOCUMENTS/INVESTIGATIONAL FILES					
1. The following files are filed properly:					
a. Approved protocol					
b. Revised protocol approved by the IERC					
c. Approved Informed Consent Form (ICF)					
d. Revised ICF approved by the IERC					
e. Investigational Brochure					
f. Ethical Clearance					
g. Clinical Trial Agreement					
h. Other communication letters with IERC and Sponsor					
i. Approved flyer or advertisement materials					
2. All the study files are filed in a locked cabinet					
II. STUDY CONDUCT					
1. All informed consent/assent forms (latest IERC approved version) are properly signed and dated by the patient, Principal Investigator/ Project Leader, LAR, and/or witness					
2. All enrolled subjects have copies of the signed ICFs					
3. Persons who obtained the ICFs are all stated in the Delegation Log					
4. All eligibility criteria are met					
5. No subject is enrolled pending IERC approval of the revised ICF					

SLMC-IERC Form #04H V07/2024

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: Clinical Research/Site Monitoring Form	SOP FORM NO.: FORM # 04H

ITEMS	Rate				RECOMMENDATIONS/REMARKS			
	N/A	0	1	2				
6. All subjects are asked to re-consent using the revised IERC-approved ICF								
7. All Case Report Forms (CRF) are accomplished within 2 weeks of the subjects' visit (Check 10% of enrolled subjects which is n=)								
8. Data in CRFs are valid when checked against the source documents (Check data for primary and secondary outcomes)								
9. All protocol deviations/violations are reported to the IERC								
10. All ADRs, SAEs and SUSARs are reported to the IERC within 24 hours to 7 days upon discovery								
III. PROGRESS REPORTS								
1. All progress reports are submitted to the IERC on time.								
2. Ethical Clearance is renewed one year from date of issuance								
3. Terminal report is submitted to the IERC								
4. Final report is submitted to the IERC								
IV. GCP CERTIFICATES/CURRICULUM VITAE/DELEGATION OF RESPONSIBILITY								
1. All GCP certificates of the study team are up-to-date								
2. All CVs of the study team are filed properly								
3. All members of the study team are included in the Delegation of Responsibility								
4. All members of the study team are trained before the start of the study								
Checklist completed by:			Noted by:					
Signature over printed name of Clinical Research Monitor _____ Date _____			Signature over printed name of Principal Investigator/Project Leader _____ Date _____					
For SLMC-IERC ONLY:								
Principal Investigator/Project Leader's Overall Performance: _____ % (Numerator: Total score; Denominator: 2 x no. of applicable items)								
IERC RECOMMENDATIONS/ACTION:								
Noted by:			Approved:					
Signature over printed name of SLMC-IERC Member _____ Date _____			Signature over printed name of SLMC-IERC Chair _____ Date _____					



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory		Revision Effective Date: April 1, 2025
SOP FORM TITLE: ICF Clinical Monitoring Form (Attachment to Clinical Research/Site Monitoring Form)		SOP FORM NO.: FORM # 04I

EC Reference No.: _____

Date: _____

Principal Investigator: _____

ICF CLINICAL MONITORING FORM

Date Enrolled	PATIENT CODE	PATIENT SIGNED	RELATIVE SIGNED	NO RELATION STATED	PERSON WHO OBTAINED THE CONSENT (Initial)	PERSON WHO OBTAINED THE CONSENT (Reconsent)	Date of Reconsent	OTHERS/REMARKS
1.								
2.								
3.								
4.								
5.								

SL-IERC Form #04I V05/2024



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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP FORM TITLE: ICF Clinical Monitoring Form (Attachment to Clinical Research/Site Monitoring Form)	SOP FORM NO.: FORM # 04I

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SOP TEMPLATE TITLE: Letter of Appointment Template	SOP TEMPLATE NO.: TEMPLATE # 01A



OFFICE OF THE PRESIDENT

<Enter Date>

<Enter Name of SLMC-IERC Member>

<Enter Position>

<Enter Address>

Dear _____,

I am pleased to inform you that you are hereby appointed as Member of the St. Luke's Medical Center Institutional Ethics Review Committee (SLMC-IERC) of St. Luke's Medical Center Quezon City and Global City effective <Enter start date> until <Enter end date>.

The primary role of the SLMC-IERC is to safeguard the rights and well-being of the human participants in research. The committee is responsible for:

1. Evaluating and Recommending Approval or Disapproval - Assess and recommend approval or disapproval of research involving human subjects, including clinical trials at SLMC, ensuring adherence to ICH-Good Clinical Practice (GCP) guidelines and ethical standards.
2. Determining Acceptability and Compliance - Review research proposals for compliance with organizational policies, local laws, professional standards, and community values, ensuring ethical propriety and cultural sensitivity.
3. Safeguarding Research Integrity - Protect the integrity of the research by identifying and addressing conflicts of interest and divided loyalties among those involved in the study to ensure objective, unbiased decision-making.
4. Primary Reviewer Responsibilities - As a Primary Reviewer, ensure the ethical conduct of clinical trials and research through both Initial and Post-Approval Reviews. This includes:
 - Evaluating the initial ethical soundness of the study, ensuring participant protection, risk minimization, and compliance with ethical guidelines.
 - Conducting post-approval review and monitoring to ensure ongoing participant safety, ethical compliance, and adherence to the approved protocol, including reviewing amendments, adverse events, protocol deviations/violations and final study reports.

Attached herein are the duties and responsibilities of the SLMC-IERC and its individual members.

By signing the CONFORME below means acceptance of this important responsibility.

Sincerely yours,

<Enter name of President and CEO>

President and CEO

CONFORME:

Signature of Member

Attachments: *Duties and Responsibilities of the SLMC-IERC Members*
List of SLMC-IERC members

SL-IERC Template # 01A V05/2025 Member



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Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Letter of Appointment Template	SOP TEMPLATE NO.: TEMPLATE # 01A

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: SLMC-IERC Roles and Responsibilities Template (Attachment to SLMC-IERC Appointment)	SOP TEMPLATE NO.: TEMPLATE # 01B

I. ROLES AND RESPONSIBILITIES OF THE SLMC-IERC
Ethical Evaluation of Research Involving Human Participants

1. The SLMC-IERC is responsible for determining if activities within a protocol qualify as research involving human participants.
2. Serving as a central review body, the SLMC-IERC reviews onsite clinical studies and research involving human subjects, including those concerning identifiable human materials or data.
3. The SLMC-IERC shall review essential documents of clinical research studies (i.e. all phases of clinical trials including investigator-initiated, observational, databank/registry and post marketing surveillance studies) submitted to SLMC-IERC to safeguard the rights, dignity and welfare of human participants.
4. The SLMC-IERC shall identify and recommend an External/Independent Consultant, a known expert, to provide additional information about a study when necessary.
5. The SLMC-IERC shall ensure that clinical research studies shall be conducted in accordance with Philippine laws and National Ethical Guidelines for Research Involving Human Participants (2022) by Philippine Health Research Ethics Board (PHREB), Declaration of Helsinki (2013 ed.), and International Conference on Harmonization (ICH) for Good Clinical Practice (GCP) E6(R2) (2016).
6. The SLMC-IERC shall recommend the approval of sponsor-initiated clinical trials and investigator-initiated research studies involving human participants based on any or all of the following conditions:
 - 6.1. all ethical issues have been addressed;
 - 6.2. the protocol is compliant with Good Clinical Practice guidelines;
 - 6.3. the protocol has been revised in accordance with the Notice of Action issued by the SLMC-IERC Secretariat to the Principal Investigator/Project Leader and the SLMC-IERC has made a continuing review of the response. (Please refer to SLMC-IERC SOP # 2.3 Review of Protocols that Require Revisions after Initial Review)

Issuance of Ethical Clearance

7. The SLMC-IERC shall issue the Ethical Clearance (EC) to indicate approval following review of the Protocol. (Refer to SLMC-IERC Form # 13A)
8. The Ethical Clearance shall indicate the dates of review, approval, validity and responsibilities of the Principal Investigator/Project Leader.
9. The Ethical Clearance shall be valid for a maximum of one (1) year. Validity may be shorter depending on the level of risk (Refer to SLMC-IERC SOP # 4.1, Section 4.1.4.1.3).
10. Extension of the validity of the Ethical Clearance shall be granted upon compliance with the following requirements:
 - 10.1. written request of the Principal Investigator/Project Leader;
 - 10.2. submission of progress report (using SLMC-IERC Form # 16);
 - 10.3. favorable evaluation of the progress report; and
 - 10.4. payment of extension fee.

Ongoing Reviews and Authority

11. The SLMC-IERC shall evaluate reports on adverse drug reactions (ADRs) / serious adverse events (SAEs) / suspected unexpected serious adverse reactions (SUSARs) and perform continuing review of each ongoing trial at intervals appropriate of the risk to human subjects or at least once a year (based on the SLMC-IERC review approval date) using the SLMC-IERC Continuing Review Report Form (SLMC-IERC Form # 16) issued by the SLMC-IERC Secretariat (Refer to policy on

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SOP TEMPLATE TITLE: SLMC-IERC Roles and Responsibilities Template (Attachment to SLMC-IERC Appointment)	SOP TEMPLATE NO.: TEMPLATE # 01B

 St. Luke's Medical Center <i>We love life.</i> INSTITUTIONAL ETHICS REVIEW COMMITTEE Monitoring of Clinical Safety of Investigational Drugs and SOP on Continuing Review Procedures, Chapter 4, SOP # 4.2). 12. Upon the recommendation of the SLMC-IERC Executive Committee Chair and appointment by the SLMC President & CEO, Regular Members may be charged with reviewing serious adverse events (SAEs). These members are responsible for ensuring that SAEs receive a prompt and expert evaluation, consistent with the participant safety and research integrity duties. 13. The SLMC-IERC shall have authority to suspend or terminate approval of human research not being conducted in accordance with the SLMC-IERC's requirements or that has been associated with unexpected serious harm to subjects. 14. The SLMC-IERC may observe or authorize the CHRP to observe, in certain occasions (e.g. numerous reports of protocol deviations / violations, onsite SAEs & SUSARs and complaints) the consent process and the conduct of the human research. 15. The SLMC-IERC shall evaluate conflict of interest (COI) of investigators and research staff and have the final authority to decide whether the COI and management plan, if any, allow the human research to be approved. II. RESPONSIBILITIES OF THE SLMC-IERC MEMBER Every Regular and Alternate Member of the SLMC-IERC shall have the following responsibilities: 1. Reviewing the minutes from previous meetings as provided via email in advance of upcoming full board meetings; 2. Safeguarding the confidentiality of all documents and discussions pertaining to SLMC-IERC deliberations and decisions; 3. Declaring any potential conflicts of interest with research protocols under review to maintain objectivity; 4. Participating consistently in SLMC-IERC meetings and engage in the review and evaluation of clinical research protocols, responding to both full and expedited review requests; 5. Engaging in ongoing evaluation processes for approved research protocols, contributing to their continuous oversight; 6. Reviewing and providing insights on progress reports, protocol amendments, adverse event reports, and instances of protocol deviation or violation; 7. Acquiring a thorough understanding of the SLMC-IERC SOP and adhere to these guidelines; 8. Participating in workshops, seminars, and conferences related to research ethics to enhance expertise and stay informed about current practices; 9. Maintaining an up-to-date Good Clinical Practice (GCP) certification, with a validity period of at least three year; 10. Providing an updated Curriculum Vitae at the initiation of each term of appointment. <i><Insert specific responsibilities as Chair, Vice Chair, Member-Secretary, Layperson, Screening and Risk Assessment, Response to NOA, Amendments, Continuing Reviews, SAEs, or Protocol Violations/Deviations as necessary></i> III. RESIGNATION, DISQUALIFICATION, WITHDRAWAL OF APPOINTMENT AND REPLACEMENT OF SLMC-IERC MEMBERS 1. An SLMC-IERC Member may resign from the SLMC-IERC at any time during his/her term by submitting a written letter addressed to the SLMC President & CEO through the SLMC-IERC Executive Chair. A copy of the letter shall be furnished to the Head of R&B.	

SL-IERC Form # 01B V05/2024 (Member)

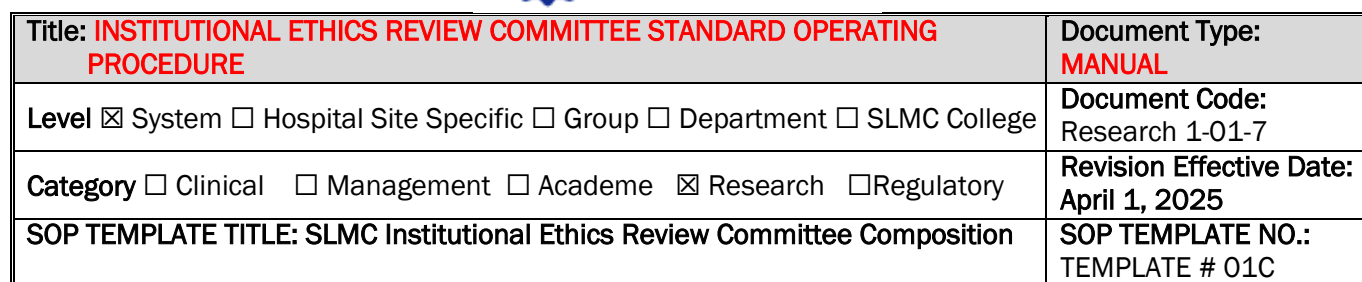


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 St. Luke's Medical Center <i>We love life.</i>	INSTITUTIONAL ETHICS REVIEW COMMITTEE
2. An SLMC-IERC Member may be recommended by the SLMC-IERC Chair for disqualification and/or withdrawal of Appointment for any of the following reasons: 2.1. Failure without justifiable reason to attend three (3) consecutive meetings of the SLMC-IERC without any valid reason or six (6) absences within a 12-month period; 2.2. Failure to disclose Conflict of Interest as herein defined. (COI refers to circumstances where a primary interest, such as patient health, is compromised by a secondary interest such as financial profit); 2.3. Violation of the Confidentiality Rule; 2.4. Other justifiable causes as determined by the SLMC-IERC. 3. Replacement of the resigned SLMC-IERC Member shall be made by the President and CEO, upon recommendation of the SLMC-IERC Chair and Head of R&B.	
SL-IERC Form # 01B V05/2024 (Member)	

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SOP TEMPLATE TITLE: SLMC Institutional Ethics Review Committee Composition	SOP TEMPLATE NO.: TEMPLATE # 01C

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Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Application of Waiver of Informed Consent	SOP TEMPLATE NO.: TEMPLATE # 02

	INSTITUTIONAL ETHICS REVIEW COMMITTEE
Dear (IERC Chair) Re: Waiver of Informed Consent for Clinical Research Study I, [Your Name], am conducting a clinical research study titled [Title of the Study] at [Your Organization/Institution]. The purpose of this study is [Brief Description of the Study]. In accordance with the ethical principles governing research involving human subjects, I am writing to request a waiver of informed consent for this study. The reasons for this request are as follows (check which applies for the study). ☐ The research involves minimal risk to participants. ☐ Obtaining informed consent would be impracticable due to [Explain the reasons, e.g., emergency situations, retrospective data analysis, etc.]. ☐ The study's objectives cannot be achieved without waiving informed consent. If you have any questions or concerns about this waiver of informed consent, please do not hesitate to contact me at [Your Contact Information]. Thank you for considering participation in this important research study. Sincerely, [Your Name] [Your Position/Title] [Your Organization/Institution]	
SLMC-IERC Template # 02 V05/2024	



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SOP TEMPLATE TITLE: Application of Waiver of Informed Consent	SOP TEMPLATE NO.: TEMPLATE # 02

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SOP TEMPLATE TITLE: Letter of Exemption from Review	SOP TEMPLATE NO.: TEMPLATE # 03A

 St. Luke's Medical Center <i>We love life.</i>	INSTITUTIONAL ETHICS REVIEW COMMITTEE
<Enter Date> <Enter Name of Proponent> <Enter Name of Proponent> <Enter Institute/Department> Dear Dr. <Surname> and Dr. <Surname>, The study entitled "<Enter Title>" from the <Enter Institute/Department> has been received and registered by the St. Luke's Institutional Scientific Review Committee (ISRC) and Institutional Ethics Review Committee (IERC). We are pleased to inform you that this study is exempted from SLMC-IERC review. Please note the following requirements applicable to this exemption as determined by the SLMC-IERC: 1. If you amend your study, it may affect the SLMC-IERC decision. An amendment must be submitted to the SLMC-IERC for re-evaluation if the study still qualifies for exemption. 2. Upon completion of the study, submit a final manuscript or final report to the SLMC-IERC. 3. As the Principal Investigator, you still have ultimate responsibility of conducting the study in accordance with good clinical practice guidelines, national ethical guidelines and SLMC's policies on human research, ensuring that the rights, safety, privacy and confidentiality, and well-being of the participant(s) involved in the study are protected. <i>Note: If case report/case study, please add:</i> Please be reminded that certain selected Journals and scientific meetings require an Informed Consent from the subject or legally acceptable representative (LAR) prior to acceptance for publication or presentation respectively. Very truly yours, <Enter Name of SLMC-IERC Chair> Chair	
SLMC-IERC Template # 3A V03/2024	



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		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
INSTITUTIONAL ETHICS REVIEW COMMITTEE		<u>NOTICE OF ACTION</u>	
<Enter Name of IERC Chair> Chair		TO: <Enter Name> Principal Investigator/s	
<Enter Name of IERC Vice-Chair> Vice-Chair		FROM: <Enter Name> Chair, Ethics Review	
Members:		RE: Clinical Trial Protocol entitled SL-_____: <Enter Title of Clinical Trial or Clinical Research Project>	
<Enter Name of Member>		DATE: <Enter Date>	
<Enter Name of Member>		This is to inform you that the St. Luke's Institutional Ethics Review Committee (IERC) has done an <full board/expedited> review of your proposal.	
<Enter Name of Member>		I. <u>Review Elements of the Protocol</u>	
<Enter Name of Member>		_____	
<Enter Name of Member>		II. <u>Review Elements of the Informed Consent</u>	
<Enter Name of Member>		_____	
<Enter Name of Member>		III. <u>Others</u>	
<Enter Name of Member>		_____	
<Enter Name of Member>		Please send your response to the above two (2) weeks after receiving the notice to facilitate continuing review of your protocol. Failure to respond within the time frame of 90 days will be considered withdrawal of the application. The submitted protocol files will be placed in the inactive file.	
Cc: <Enter Sponsor/CRO/ARO>		If you have any questions or clarifications, please call <Enter Name> of the Secretariat at 8723-0101 local 7391.	
		Thank you.	
SLMC-IERC Template #03B V05/2024			

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SOP TEMPLATE TITLE: Notice of Action	SOP TEMPLATE NO.: TEMPLATE # 03B

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SOP TEMPLATE TITLE: Summary of Revisions	SOP TEMPLATE NO.: TEMPLATE # 03C

SUMMARY OF THE REVISIONS

IERC Recommendations/Clarifications	Investigator's Response



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SOP TEMPLATE TITLE: Summary of Revisions	SOP TEMPLATE NO.: TEMPLATE # 03C

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SOP TEMPLATE TITLE: SLMC-IERC Reviewer Composition Template	SOP TEMPLATE NO.: TEMPLATE # 03D



**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

INSTITUTIONAL ETHICS REVIEW COMMITTEE COMPOSITION

EC Reference No:
 TITLE:

MEMBER (TITLE AND NAME)	OCCUPATION (DESIGNATION)	INSTITUTION	TICK (✓) IF PRESENT WHEN ABOVE ITEMS WERE REVIEWED
<Insert Name> Chair			
<Insert Name> Vice-Chair			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			
<Insert Name> Member			

Comments:

I hereby confirm that this Independent Ethics Committee was organized and operates according to ICH-GCP applicable laws and regulations.

<Insert Name>
 Chair, Institutional Ethics Review Committee

Cc: SLMC-IERC

SLMC-IERC Template #03D V05/2024 (Approval)



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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SOP TEMPLATE TITLE: SLMC-IERC Reviewer Composition Template	SOP TEMPLATE NO.: TEMPLATE # 03D



**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

NOTICE OF ACTION

INSTITUTIONAL ETHICS REVIEW COMMITTEE COMPOSITION

EC Reference No:
TITLE:

MEMBER (TITLE AND NAME)	OCCUPATION (DESIGNATION)	INSTITUTION	TICK (✓) IF PRESENT WHEN ABOVE ITEMS WERE REVIEWED
<Insert Name> <i>Chair</i>			
<Insert Name> <i>Vice-Chair</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			
<Insert Name> <i>Member</i>			

Comments:

I hereby confirm that this Independent Ethics Committee was organized and operates according to ICH-GCP applicable laws and regulations.

DATE OF REVIEW:

Cc: SL-IERC

<Insert Name>
Chair, Institutional Ethics Review Committee

SLMC-IERC Template #03D V05/2024 (For Notice of Action)

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SOP TEMPLATE TITLE: Principal Investigator and Study Team Acknowledgment of Responsibilities	SOP TEMPLATE NO.: TEMPLATE # 03E



INSTITUTIONAL ETHICS REVIEW COMMITTEE

EC Reference No:

Title:

PRINCIPAL INVESTIGATOR AND STUDY TEAM ACKNOWLEDGMENT OF RESPONSIBILITIES

General Responsibilities (Applicable to All Research)

- Compliance:** Comply with Medical Center policies and procedures and promptly notify Sponsor/CRO (if applicable) of any conflicts with hospital policies.
- Team Training:** Ensure all study team members have valid Good Clinical Practice (GCP) training (3 years validity) and understand their research obligations.
- Delegation:** Delegate duties and responsibilities to study team following applicable laws and ensure tasks align with team member qualifications.
- Ethics Review Process:** Explain to participants/relatives how clinical research protocols are reviewed and approved by the Institutional Ethics Review Committee (SLMC-IERC).
- Informed Consent:** Obtain informed consent during the screening process. The PI or a designated, qualified member of the study team ensures they are competent to answer all relevant questions concerning the study. A signed written informed consent form (version approved by SLMC-IERC) is obtained from each subject, or their legally authorized representative, for participation in the study and for the fair and lawful processing of data obtained for the research.
- Study Conduct:** Conduct the research according to the approved protocol, applicable institutional policies, and ethical guidelines.
- Recordkeeping:** Maintain adequate and accurate records and source documents for the research, making them readily available for inspection by the SLMC-IERC and/or regulatory authorities.
- Protocol Deviation/violation Reporting:** Submit reports of any deviation/violation using from approved protocol to the SLMC-IERC for subject safety or data integrity.
- Progress Reporting:** Submit progress reports as specified by IERC and annual reports 30 days before expiry of Ethical Clearance using (#13C) for renewal of ethical clearance.
- Protocol/ICF Amendments:** Report any protocol or ICF changes using Form, especially those affecting subject safety, change in study team to the SLMC-IERC within for review and approval before implementation.
- SLMC-IERC Communication:** Report any event with ethical significance and provides information needed by the SLMC-IERC for ongoing review in a timely manner.
- Early Termination:** Inform the SLMC-IERC in writing of early termination due to reasons other than completion, including but not limited to: Insufficient enrollment, safety concerns identified during the study, funding issues, ineffectiveness of the intervention.
- Completion:** Submit Final Report using Form and Manuscript or Close-out reports (for sponsored clinical trials) when data collection and participant recruitment are finished.
- Confidentiality:** Maintain confidentiality of subject data and protect their privacy throughout the research process, adhering to the Data Privacy Act of 2012 and ethical guidelines.

Additional Responsibilities for Clinical Trials

- Qualifications:** Ensure study team have valid and current PRC license and possess qualifications and training appropriate for their assigned roles in the study.

SLMC-IERC Template # 3E V06/2024

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SOP TEMPLATE TITLE: Principal Investigator and Study Team Acknowledgment of Responsibilities	SOP TEMPLATE NO.: TEMPLATE # 03E

2. **Commencement of Clinical Trials:** Start clinical trial only after a fully executed contract is in place, signed by all required parties.
3. **Subject Data Management:** Review all Subject Case Report Forms (CRFs) for accuracy and completeness of data. Provides CRFs and study data in the agreed-upon format as stipulated in the contract.
4. **Timely Reporting:** Complies with time schedules for data submission as defined in the contract and corrects errors in CRFs promptly.
5. **Subject Identification:** Issues identification cards to enrolled participants and tags medical charts/electronic medical records of admitted patients in clinical trials.
6. **Study Team Insurance:** Ensures the study team has adequate malpractice insurance as required by the hospital and research contract.
7. **Medical Care:** Provides reasonable medical care for study subjects for medical problems arising during participation that are, or could be, related to the study intervention.
8. **Access to Medical Care:** Provides reasonable access to needed medical care, either by the investigator or another qualified individual.
9. **Adverse Event Reporting:** Reports all adverse drug reactions (ADRs), serious adverse events (SAEs), and suspected unexpected serious adverse reactions (SUSARs) using the designated SLMC-IERC Form (#14) following specific timeframes:
 - o Fatal or Life-threatening SAEs and SUSARs: Reported upon discovery but no later than 7 calendar days, followed by a complete report.
 - o All other SAEs and SUSARs that are not fatal or life-threatening: Reported no later than 15 calendar days after discovery. Updated or follow-up reports shall be submitted periodically until resolution of the event.
 - o For SAEs and SUSARs occurring outside SLMC (local or international): Submit soft copies of line listing or summary report on a quarterly basis.
10. **Sponsor/CRO Monitoring Report:** Submits to the SLMC-IERC copies of the "Follow-up Report or Correspondence to the Principal Investigator" furnished by the Sponsor/CRO after their monitoring visit

Acknowledgment:

By signing below, we acknowledge that we have read and understood the responsibilities outlined in this document for the specific research project [insert project name]. We understand that these responsibilities are essential for the ethical and compliant conduct of research.

Designation	Name and Signature	Date
Principal Investigator/ Project Leader		
Study Team Members (if applicable)		



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SOP TEMPLATE TITLE: Elements for Presentation during Full Board Review of Clinical Research Protocols	SOP TEMPLATE NO.: TEMPLATE # 03F

 St. Luke's Medical Center <i>We love life.</i>	INSTITUTIONAL ETHICS REVIEW COMMITTEE
Elements for Presentation during Full Board Review of Clinical Research Protocols - EC Reference Number and Protocol Title - Principal Investigator/Project Leader - Sponsor - Conflict of interest of Principal Investigator/Project Leader - Social and scientific value - Scientific validity, study design - Fair selection of subjects - Inclusion/exclusion Criteria - Justification for inclusion of vulnerable subjects - Justifiable use of placebo, if applicable - Standard of care - Withdrawal criteria - Risks-benefits assessment - Recruitment process - Ethical considerations - Informed Consent form - Insurance - Issues on the protocol	
SLMC-IERCTemplate #03C V05/2024	

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SOP TEMPLATE TITLE: Elements for Presentation during Full Board Review of Clinical Research Protocols	SOP TEMPLATE NO.: TEMPLATE # 03F

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SOP TEMPLATE TITLE: SLMC-IERC Meeting Attendance Sheet	SOP TEMPLATE NO.: TEMPLATE # 03G



St. Luke's
Medical Center
We love life.

**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

IERC MEETING ATTENDANCE SHEET

<Insert Date>

<Insert Time>

<u>NAME</u>	<u>SIGNATURE</u>
Chair: <Enter Name>	_____
Vice Chair: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Member: <Enter Name>	_____
Alternate Member:	
<Enter Name>	_____

SLMC-IERC Template # 03G V05/2024



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: SLMC-IERC Meeting Attendance Sheet	SOP TEMPLATE NO.: TEMPLATE # 03G

		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
Secretariat:	<Enter Name>	_____	
	<Enter Name>	_____	
	<Enter Name>	_____	
SLMC-IERC Template # 03G V05/2024			



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Response to Query or Complaint Template	SOP TEMPLATE NO.: TEMPLATE # 03H

 INSTITUTIONAL ETHICS REVIEW COMMITTEE	
INSTITUTIONAL ETHICS REVIEW COMMITTEE <Name of Chair> <i>Chair</i> <Name of Vice Chair> <i>Vice-Chair</i> Members: Members: <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> <Name of Member> Cc: N/A	[Date] [Complainant Name] [Complainant Address] Subject: Re: Query/Complaint Regarding [Briefly state subject, e.g., Research Project, General Concern] Dear [Complainant Name], This letter addresses your recent query/complaint received on [Date of Receipt]. [Choose ONE of the following options, and adjust the wording accordingly:] Option 1 (Query Addressed): The information you requested is as follows: [Provide the requested information] Option 2 (Complaint Investigated): Our investigation has been completed. [Briefly state the outcome: "The complaint was substantiated/not substantiated."] [If applicable: Briefly state the reason for the decision and any corrective actions taken.] Option 3 (Complaint Partially Substantiated): Our investigation found [briefly state the substantiated aspects of the complaint]. [Briefly state the aspects of the complaint that were not substantiated.] [If applicable: Briefly state the corrective actions taken.] We appreciate you bringing this matter to our attention. Sincerely, [Name and Title of IERC Chair/Authorized Representative]

SLMC-IERC Form # 03H Response to Query or Complaint V01/2025

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Response to Query or Complaint Template	SOP TEMPLATE NO.: TEMPLATE # 03H

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Memo (For Renewal of Ethical Clearance)	SOP TEMPLATE NO.: TEMPLATE # 04A

RESEARCH AND BIOTECHNOLOGY Institutional Ethics Review Committee <u>M E M O</u> TO: <Enter name of PI/Project Leader> <Enter Institute/Department> FROM: <Enter name of IERC Chair> IERC Chair RE: Extension of Ethical Clearance for Clinical Trial entitled: <SL-_____: Enter Title of Clinical Trial Research> DATE: <Enter Date> INSTITUTIONAL ETHICS REVIEW COMMITTEE In accordance with the SOP of the Institutional Ethics Review Committee, Ethical Clearance is valid for <one (1) year/six (6) months/three (3) months>. In this regard please be informed that based on the Ethical Clearance issued to you, the Continuing Review/Progress Report Form shall be submitted <annually/semi-annually/quarterly> from date of approval which is <Enter Date of Approval>. Non-receipt of your continuing review/progress report will entail revocation of your Ethical Clearance thus it is understood that all clinical research activities will be suspended. Please disregard this notice if the Clinical <Trial/Research> Project has been closed-out and inform the SL-IERC on the details of the study closure. Should you have any questions, please do not hesitate to contact the IERC Secretariat local 5562. Thank you for your attention.	

SLMC-IERCTemplate # 04A V05/2024



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Memo (For Renewal of Ethical Clearance)	SOP TEMPLATE NO.: TEMPLATE # 04A

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: SAE Notice of No Action Template	SOP TEMPLATE NO.: TEMPLATE # 04B

		INSTITUTIONAL ETHICS REVIEW COMMITTEE	
INSTITUTIONAL ETHICS REVIEW COMMITTEE		NOTICE OF ACTION	
<Name of Chair> Chair		TO: <Name of Principal Investigator> Principal Investigator	
<Name of Vice Chair> Vice-Chair		FROM: <Name of Chair> Chair, Institutional Ethics Review Committee	
Members:		RE: SAE Report	
<Name of Member>		TITLE: Sponsor-Initiated Trial: SL-_____:	
<Name of Member>		DATE: _____	
<Name of Member>		The full board has reviewed your submitted Serious Adverse Event report	
<Name of Member>		on _____ for the participant:	
<Name of Member>		Subject No. and Initial: _____	
<Name of Member>		SAE Diagnosis: _____	
<Name of Member>		Type of Report: _____	
<Name of Member>		The resolution for such is review are as follows:	
<Name of Member>		<No further action is required>	
<Name of Member>		Thank you very much.	
Cc: N/A			
SLMC-IERC Form # 04B V07/2024			



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: SAE Notice of No Action Template	SOP TEMPLATE NO.: TEMPLATE # 04B

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: PD/PV Notice of No Action Template	SOP TEMPLATE NO.: TEMPLATE # 04C



St. Luke's
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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

INSTITUTIONAL ETHICS REVIEW COMMITTEE

<Name of Chair>
Chair

<Name of Vice Chair>
Vice-Chair

Members:

Members:

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

<Name of Member>

Cc: N/A

NOTICE OF ACTION

TO: <Name of Principal Investigator>
Principal Investigator

FROM: <Name of Chair>
Chair, Institutional Ethics Review Committee

RE: **Protocol Deviation/Violation Report**

TITLE: **Sponsor-Initiated Trial: SL-_____:**

DATE: _____

The full board has reviewed your submitted Protocol Deviation/Violation report on _____ for participant:

Subject No. and Initial: _____

Characterization: _____

The resolution for such is review are as follows:

No further action is required.

Thank you very much.

SLMC-IERC Form # 04C V04/2024



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: PD/PV Notice of No Action Template	SOP TEMPLATE NO.: TEMPLATE # 04C

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Notice of Approval Template	SOP TEMPLATE NO.: TEMPLATE # 04D

St. Luke's Medical Center <i>We love life.</i> <u>NOTICE OF APPROVAL</u> TO: <Enter Name of Pls/Project Leaders> <Enter Institute/Department> FROM: <Enter Name of IERC Chair> Chair, Institutional Ethics Review Committee RE: SL-_____ : <Enter Title of Clinical Research> DATE: <Enter Date> This is to inform you that the St. Luke's Institutional Ethics Review Committee (IERC) has done a (full board or expedited review) on your above protocol. (Expedited review is done by the IERC Chair or a designated voting member or subgroup of voting members rather than by the entire Committee.) The following submitted documents have been reviewed and approved <Enter Date> for use in the study: - Approved protocol <Enter version no., date> - Approved ICF <Enter version no., date> - Approved advertisement materials (if applicable) <Enter date> - Case report form (or data collection form) (if applicable) <Enter version no., date> - Patient's diary (if applicable) Pertinent documents shall be included in your original protocol for filing purposes. Please be reminded that the study must be conducted according to the approved proposal, and compliance to the same shall be monitored. Any subsequent amendments to the protocol must be brought to the attention of the Committee for re-approval. Once the study is completed, two (2) copies of the research paper must be submitted for filing. If you have any questions or clarifications, please call the Secretariat at 8727-5562 or 8723-0101 local 7391. For your information and guidance. SLMC-IERC TEMPLATE # 04D V07/2024	INSTITUTIONAL ETHICS REVIEW COMMITTEE



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Notice of Approval Template	SOP TEMPLATE NO.: TEMPLATE # 04D

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Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Clinical Research/Site Monitoring Notice	SOP TEMPLATE NO.: TEMPLATE # 04E



Research and Biotechnology Group
Office of Research Integrity

CLINICAL RESEARCH/SITE MONITORING NOTICE FORM

Monitoring Visit No.	:	_____	Monitoring Date	:	_____
Principal Investigator	:	_____	EC Reference no.	:	_____
Project Coordinator	:	_____	IERC Approval Date	:	_____
Institute/Department	:	_____	Status of the Study	:	_____
Protocol Title	:	_____			

Date _____

Dear _____,

In compliance with Good Clinical Practice Guidelines, please be informed that our Clinical Research Monitor, _____ is scheduled to review the records of the above-mentioned Clinical Trial.

Please advise Project Coordinator, Fellow, Clinical Research Coordinator, Research Assistant or any person in-charge of the above-mentioned study to make the records available to <Enter Name of Clinical Research Monitor> on <Enter date of monitoring>.

Please confirm schedule of visit at local 8723-0101 local #'s 7391 and 5562.

For your compliance. Thank you.

Sincerely yours,

<Enter Name>
Associate Director
Office of Research Integrity
Research and Biotechnology

Noted:

<Enter Name>
Chair, Institutional Ethics Review Committee

SLMC-IERC Template #04E V7/2024

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Clinical Research/Site Monitoring Notice	SOP TEMPLATE NO.: TEMPLATE # 04E

ITEMS TO BE MONITORED

I. PATIENT RECRUITMENT SUMMARY

1. Total no. of required subjects
2. Total no. of screened subjects
3. Total no. of enrolled subjects
4. Total no. of screening failure
5. Total no. of signed ICF
6. Total no. of drop-outs
7. Total no. of subjects withdrawn
8. Total no. of subjects completed

II. SOURCE DOCUMENTS/INVESTIGATIONAL FILES

1. The following files are filed properly:
 - a. Approved protocol
 - b. Revised protocol approved by the IERC
 - c. Approved Informed Consent Form (ICF)
 - d. Revised ICF approved by the IERC
 - e. Investigational Brochure
 - f. Ethical Clearance
 - g. Clinical Trial Agreement
 - h. Other communication letters with IERC and Sponsor
 - i. Approved flyer or advertisement materials
2. All the study files are filed in a locked cabinet

III. STUDY CONDUCT

1. All informed consent/assent forms are properly signed and dated by the patient, Principal Investigator/Project Leader, LAR, and/or witness
2. All enrolled subjects have copies of the signed ICFs
3. Persons who obtained the ICFs are all stated in the Delegation Log
4. All medical charts of patients enrolled in clinical trials have copies of the signed ICF
5. All eligibility criteria are met
6. No subject is enrolled pending IERC approval of the revised ICF
7. All subjects are asked to re-consent using the revised IERC-approved ICF
8. All Case Report Forms (CRF) are accomplished within 2 weeks of the subjects' visit
9. Data in CRFs are valid when checked against the source documents
10. All protocol deviations/violations are reported to the IERC
11. All ADRs, SAEs and SUSARs are reported to the IERC within 24 hours to 7 days upon discovery

IV. PROGRESS REPORTS

1. All progress reports are submitted to the IERC
2. Ethical Clearance is renewed one year from date of issuance
3. Terminal report is submitted to the IERC
4. Final report is submitted to the IERC

V. GCP CERTIFICATES/CURRICULUM VITAE/DELEGATION OF RESPONSIBILITY

1. All GCP certificates of the study team are up-to-date
2. All CVs of the study team are filed properly
3. All members of the study team are included in the Delegation of Responsibility
4. All members of the study team are trained before the start of the study

NOTE: Kindly prepare a copy of the following:

1. Updated *Curriculum Vitae* of all study team members
2. GCP Certificates of all study team members
3. Latest follow-up report

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Agenda Template	SOP TEMPLATE NO.: TEMPLATE # 05A

 St. Luke's Medical Center <i>We love life.</i>	INSTITUTIONAL ETHICS REVIEW COMMITTEE																																												
AGENDA <Insert Date> R&B Conference Room 6 th East St. Luke's Medical Center Quezon City																																													
1. Call to order 2. Invocation 3. Determination of quorum and presence of non-institutional members 4. Disclosure of Conflict of interest 5. Approval of the Agenda of the Meeting 6. Reading and approval of the Minutes of the previous meeting 7. Matters arising from the Minutes of the previous meeting 8. Full Board Review of Clinical Trial Protocols 8.1. Sponsor-initiated Trial <table border="1"> <tr><td>EC Reference No.:</td><td></td></tr> <tr><td>Protocol Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> <tr><td>Protocol Type</td><td></td></tr> <tr><td>Primary Reviewer</td><td></td></tr> </table> 8.2. Investigator-initiated Clinical Researches (Copy template used in 8.1 above) 8.3. Response to Notice of Action <table border="1"> <tr><td>EC Reference No.</td><td></td></tr> <tr><td>Protocol Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> <tr><td>Protocol Type</td><td></td></tr> <tr><td>Quorum Status</td><td></td></tr> <tr><td>Conflict of interest</td><td></td></tr> <tr><td>Primary Reviewer</td><td></td></tr> <tr><td>Other Reviewers</td><td></td></tr> <tr><td colspan="2">REVIEW ELEMENTS</td></tr> <tr><td>Issues</td><td>•</td></tr> <tr><td>Comments</td><td>•</td></tr> <tr><td>Recommendations</td><td>•</td></tr> </table> 8.4. Protocol Amendments <table border="1"> <tr><td>EC Reference No.</td><td></td></tr> <tr><td>Protocol Title</td><td></td></tr> <tr><td>Principal investigator</td><td></td></tr> </table>		EC Reference No.:		Protocol Title		Principal Investigator		Sponsor		Protocol Type		Primary Reviewer		EC Reference No.		Protocol Title		Principal Investigator		Sponsor		Protocol Type		Quorum Status		Conflict of interest		Primary Reviewer		Other Reviewers		REVIEW ELEMENTS		Issues	•	Comments	•	Recommendations	•	EC Reference No.		Protocol Title		Principal investigator	
EC Reference No.:																																													
Protocol Title																																													
Principal Investigator																																													
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Quorum Status																																													
Conflict of interest																																													
Primary Reviewer																																													
Other Reviewers																																													
REVIEW ELEMENTS																																													
Issues	•																																												
Comments	•																																												
Recommendations	•																																												
EC Reference No.																																													
Protocol Title																																													
Principal investigator																																													
SLMC-IERC Meeting Tentative Agenda <Enter Date of Meeting> SLMC-IERC #05A V05/2024																																													

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Agenda Template	SOP TEMPLATE NO.: TEMPLATE # 05A


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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

Sponsor	
Document Submitted	•
Status/Remarks	•
IERC Action	•

8.5. Continuing Review/Progress Report/Terminal Report

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Document Submitted	•
Status/Remarks	•
IERC Action	•

8.6. Protocol Deviation/Violation

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Member-in Charge	
Primary Reviewer	
Characterization	•
Corrective Action	•
IERC Action	•

8.7. SAE

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Principal investigator	
Document Submitted	•
Status/Remarks	•
IERC Action	•

8.8. Study Site Monitoring Visit

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Principal investigator	
Document Submitted	•

SLMC-IERC Meeting Tentative Agenda <Enter Date of Meeting>
SLMC-IERC #05A V05/2024



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Agenda Template	SOP TEMPLATE NO.: TEMPLATE # 05A

	INSTITUTIONAL ETHICS REVIEW COMMITTEE

Status/Remarks	•
IERC Action	•

9. Matters for Information

9.1 ANNEX 1 Updates on protocols reviewed and discussed

1. Full board review

A. Sponsor-initiated

EC Reference No. and Title:

Principal investigator/s:

Sponsor:

Primary Reviewer:

Sponsored by:

Status/Remarks:

B. Response to Notice of Action

(Copy template as 9.1.1.a above)

2. Expedited review

Investigator-initiated

Study Team	
Department/Institute	
Reviewers	
Status/Remarks	
Date of action	

3. Exempted from Review (Copy template as 9.1.2 above)

9.2 ANNEX 2 Protocol amendments

Principal investigator	
Submitted documents	
Comments	
Status/Remarks	
Date of action	

9.3 ANNEX 3 Response to Notice of Action (Copy template as 9.1.2 above)

9.4 ANNEX 4 Study updates

1. Study Withdrawals/Study Close Out/Study Termination

Principal investigator	
Document Submitted	
Status/Remarks	
Date of action	

2. Protocol Deviation/Violation (Copy template as 9.4.1 above)

3. Continuing Review (Copy template as 9.4.1 above)

9.5 ANNEX 5 Safety reports (Copy template as 9.1.2 above)

9.6 ANNEX 6 Materials for information and acknowledgment (Copy template as 9.1.2 above)

10. Announcements:

11. Other matters:

SLMC-IERC Meeting Tentative Agenda <Enter Date of Meeting>
SLMC-IERC #05A V05/2024



Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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SOP TEMPLATE TITLE: Agenda Template	SOP TEMPLATE NO.: TEMPLATE # 05A

	INSTITUTIONAL ETHICS REVIEW COMMITTEE
12. Schedule of Next Meeting: <Enter Date> 13. Adjournment: <Enter Time>	
Prepared by: <Enter Name> IERC Member Secretary	Noted by: <Enter Name> Chair
SLMC-IERC Meeting Tentative Agenda <Enter Date of Meeting> SLMC-IERC #05A V05/2024	

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Minutes of Meeting Template	SOP TEMPLATE NO.: TEMPLATE # 05B



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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

MINUTES OF THE MEETING
 <Insert Date>
 R&B Conference Room
 6th East St. Luke's Medical Center Quezon City

ATTENDANCE

PRESENT	
<Insert Name of IERC Chair, specialization, affiliate/non-affiliate> <Insert Name of IERC Vice-Chair, specialization affiliate/non-affiliate> <Insert Name of IERC Member-Secretary, specialization affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Membe,specialization, affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Member, specialization, affiliate/non-affiliate> <Insert Name of IERC Membe, specialization, affiliate/non-affiliate>	
Absent <Insert Name>	

1. Call to order
2. Invocation
3. Determination of quorum and presence of non-institutional members
4. Approval of the Agenda
5. Disclosure of Conflict of interest
6. Reading and approval of the Minutes of the previous meeting
7. Matters arising from the Minutes of the previous meeting
8. Full Board Review of Clinical Trial Protocols
 - 8.1. Sponsor-initiated Trial

EC Reference No.:	
Protocol Title	
Principal Investigator	

IERC Minutes of the Meeting <Enter Date>
 SLMC-IERC Form #05C V03/2024

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒ System ☐ Hospital Site Specific ☐ Group ☐ Department ☐ SLMC College	Document Code: Research 1-01-7
Category ☐ Clinical ☐ Management ☐ Academe ☒ Research ☐ Regulatory	Revision Effective Date: April 1, 2025
SOP TEMPLATE TITLE: Minutes of Meeting Template	SOP TEMPLATE NO.: TEMPLATE # 05B


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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

Sponsor	
Protocol Type	
Quorum Status	
Conflict of interest	
Primary Reviewer	
REVIEW ELEMENTS	
Qualifications of PI	•
COI of PI	•
Social and Scientific Value	•
Scientific validity/design	•
Selection of subjects	•
Inclusion/exclusion Criteria	•
Vulnerability	•
Justifiable use of placebo	•
Standard of Care	•
Withdrawal criteria	•
Risks-benefits assessment	•
Recruitment process	•
Data storage	•
ICF	•
Insurance	•
Recommendations	•
Summary of recommendations	• Protocol-related issues: • Ethical-related and data privacy issues in the ethical consideration section: • Informed consent-related issues:
SL-IERC ACTION <i>(Approved; Disapproved; Deferred: minor revisions; major revisions)</i>	
Risk Assessment:	<Enter Risk (Low; Moderate; High)>: <Enter no. of members>
Protocol	<Enter Action (Approved; Disapproved; Deferred: minor/major revisions)>: <Enter no. of members>
ICF	<Enter Action (Approved; Disapproved; Deferred: minor/major revisions)>: <Enter no. of members>
IERC Action on <Protocol/Response to NOA>:	
Quorum Status	

8.2. Investigator-initiated Clinical Researches
(Copy template used in 8.1 above)

8.3. Response to Notice of Action

EC Reference No.	
Protocol Title	

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**INSTITUTIONAL ETHICS
REVIEW COMMITTEE**

Principal Investigator	
Sponsor	
Protocol Type	
Quorum Status	
Conflict of interest	
Primary Reviewer	
Other Reviewers	
REVIEW ELEMENTS	
Issues	•
Comments	•
Recommendations	•
Quorum Status	

8.4. Protocol Amendments

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Document Submitted	•
Status/Remarks	•
IERC Action	•
Quorum Status	

8.5. Continuing Review/Progress Report/Terminal Report

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Document Submitted	•
Status/Remarks	•
IERC Action	•
Quorum Status	

8.6. Protocol Deviation/Violation

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Member-in Charge	
Primary Reviewer	
Characterization	•
Corrective Action	•

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9. Matters for Information																					
9.1 ANNEX 1 Updates on protocols reviewed and discussed																					
1. Full board review																					
A. Sponsor-initiated																					
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3. Exempted from review (Copy template as 9.1.2 above)											
9.2 ANNEX 2 Protocol amendments <table border="1"> <tr> <td>Principal investigator</td> <td></td> </tr> <tr> <td>Submitted documents</td> <td></td> </tr> <tr> <td>Comments</td> <td></td> </tr> <tr> <td>Status/Remarks</td> <td></td> </tr> <tr> <td>Date of action</td> <td></td> </tr> </table>		Principal investigator		Submitted documents		Comments		Status/Remarks		Date of action	
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9.3 ANNEX 3 Response to Notice of Action (Copy template as 9.1.2 above)											
9.4 ANNEX 4 Study updates 1. Study Withdrawals/Study Close Out/Study Termination <table border="1"> <tr> <td>Principal investigator</td> <td></td> </tr> <tr> <td>Document Submitted</td> <td></td> </tr> <tr> <td>Status/Remarks</td> <td></td> </tr> <tr> <td>Date of action</td> <td></td> </tr> </table>		Principal investigator		Document Submitted		Status/Remarks		Date of action			
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3. Continuing Review (Copy template as 9.4.1 above)											
9.5 ANNEX 5 Safety reports (Copy template as 9.1.2 above)											
9.6 ANNEX 6 Materials for information and acknowledgment (Copy template as 9.1.2 above)											
10. Announcements:											
11. Other matters:											
12. Schedule of Next Meeting: <Enter Date>											
13. Adjournment: <Enter Time>											
Prepared by: <Enter Name> IERC Member Secretary	Noted by: <Enter Name> Chair										
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6. ACRONYMS

ADR	Adverse drug reaction
AE	Adverse event
ARO	Academic Research Organization
CCR	Center for Clinical Research
CCT	Center for Clinical Trials
CFR	Code of Federal Regulations
CCR	Center for Clinical Research
CHRP	Center for Human Research Protection
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case report form
CRMF	Clinical Research/Site Monitoring Form
CRO	Contract Research Organization
CRRF	Continuing Review/Progress Report Form
CT	Clinical trial
DOH	Department of Health
DOST	Department of Science and Technology
ERC	Ethics Review Committee
FDA	Food and Drug Administration
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICF	Informed consent form
ICH	International Conference on Harmonisation
IERC	Institutional Ethics Review Committee
IIT	Investigator-initiated research studies involving human subjects
IP	Investigational product
ISRC	Institutional Scientific Review Committee
JCI	Joint Commission International
LAR	Legally Acceptable Representative
MOM	Minutes of meeting
NEGHRR	National Ethical Guidelines for Health and Health Related Research
NOA	Notice of Action

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ORI	Office of Research Integrity
PCHRD	Philippine Council for Health Research and Development
PD	Protocol deviation
PFDA	Philippine Food and Drug Administration
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PL	Project Leader
PV	Protocol violation
R&B	Research and Biotechnology
REC	Research Ethics Committee
SAE	Serious adverse event
SIDCER	Strategic Initiative for Developing Capacity in Ethical Review
SiT	Sponsor-initiated clinical trials
SJREB	Single Joint Research Ethics Board
SLEC	St. Luke's Extension Clinic
SLMC	St. Luke's Medical Center
SLMCCM	St. Luke's Medical Center College of Medicine
SOP	Standard Operating Procedure
SUSAR	Suspected unexpected serious adverse reaction
WHO	World Health Organization
WMA	World Medical Association

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7. DEFINITION OF TERMS

Adverse drug reaction (ADR) - In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase “responses to a medicinal product” means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Regarding marketed medicinal products: A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. [ICH-GCP E6(R2), 2016]

Adverse event (AE) - any untoward or unfavorable medical occurrence in a human subject including any abnormal sign (e.g. abnormal physical exam or laboratory finding) symptom or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 ICH-GCP E6); encompasses both physical and psychological harms occurring commonly in biomedical research but occasionally can occur in social and behavioral research.

Amendment to the protocol - a written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. See also protocol amendment.

Approval - a favorable or affirmative decision of the Research Ethics Committee following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee, CPG, the institution, and relevant regulatory terms; the affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements. [ICH-GCP E6(R2), 2016]

Assent - authorization for one's own participation in research given by a minor or another subject who lacks the capability to give informed consent. The assent is a requirement for research in addition to consent given by a parent or legal guardian; it is agreement by an individual not



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competent to give legally valid informed consent like a child or cognitively impaired person to participate in research. See also child's assent and surrogate assent.

Case Report form (CRF) - a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. [ICH-GCP E6(R2), 2016]

Center for Human Research Protection (CHRP) - a Center of the SLMC Research and Biotechnology Office of Research Integrity responsible for the implementation of the human research protection program. It ensures that the rights, safety, and well-being of human subject participants are protected through the following activities: capacity building for the IERC members, conduct of regular training-workshops on ICH-GCP and research ethics in the Medical Center, symposium on research integrity, lay forum on clinical trials or clinical research studies and the patients' rights and responsibilities as human research participants, site initiation meetings with study team, clinical research monitoring, and ensuring that the St. Luke's IERC complies with the local applicable laws and regulations by maintaining its accreditation by the Philippine Health Research Ethics Board (PHREB) and recognition by the WHO SIDCER Forum for Ethics Review Committees in Asia and the Western Pacific (FERCAP).

Center for Clinical Trials (CCT) - This is one of the Centers of the Research and Biotechnology Group of St. Luke's Medical Center-Quezon City that provides assistance to individuals or companies who want to conduct investigator-initiated or sponsor-initiated clinical studies/trials. The Department as a "one-stop-shop" is responsible for financial and contract management for the trial, provides assistance for site-feasibility studies, coordinates with Pharmacy Services for the handling, dispensing and storage of investigational drugs, coordinates with different ancillary units and Nursing Care Group for services required, and handles the processing and storage of biological specimens for sponsor-initiated trials.

Clinical research - a study undertaken involving a particular person or group of people with the purpose of increasing knowledge and determining how well treatment or diagnostic test works in a particular patient population. The NIH-USA defines clinical research as: Patient-oriented research involves a particular person or group of people or uses materials from humans. This research can include: studies of mechanisms of human disease; studies of therapies or interventions for disease; clinical trials and studies to develop new technology related to disease. Epidemiological and behavioral studies examine the distribution of disease, the factors that affect health, and how

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people make health-related decisions. Outcomes and health services research seeks to identify the most effective and most efficient interventions, treatments, and services.”

Clinical research monitoring - the act of overseeing the progress of a clinical trials and research studies involving human participants, ensuring that it is conducted in accordance with the protocol, GCP, and local and international guidelines and regulations on research. [Adapted from the ICH-GCP E6(R2) 2018 definition of monitoring]

Clinical trial/study - a planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life.

It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

It is also defined as investigative work to evaluate new drugs, medical devices, biologics, or other interventions to patients in strictly scientifically controlled settings. Clinical trials may be designed to assess the safety and efficacy of an experimental therapy, to assess whether the new intervention is better than standard therapy, or to compare the efficacy of two standard or marketed interventions. *See also clinical research.*

Conflict of Interest - circumstance that creates a risk that professional judgments or actions concerning a primary interest (e.g., obtaining scientifically valid results, promoting and protecting the integrity of research, safety and well-being of research participants, etc.) will be unduly influenced by a secondary interest (e.g., personal or financial gain, career advancement, etc.) (adapted from Lo & Fields, 2009).

Contract Research Organization (CRO) - a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH-GCP E6(R2), 2016]

Dossier - a file containing detailed records on a particular person or subject. (Merriam-Webster Dictionary)



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Ethical clearance - a certification that a research proposal has complied with ethical requirements; action of an ethics review committee on a research protocol that signifies approval and permission to proceed with the research. *See also approval.*

Ethics review - the evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted.

Ethics review committee (ERC) - also called research ethics committee (REC), institutional ethics review board (IERB), independent ethics committee (IEC) or institutional review board (IRB) - committee constituted to review the ethical aspects of a research proposal and its possible implementation. This is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection. *See also research ethics committee, Institutional Ethics Review Committee.*

Expedited review - an ethics review of research protocol by the IRB chair or a designated voting member or subgroup of voting members rather than by the entire IRB. This is done for some research involving no more than minimal risk and maybe for minor changes in approved research, annual renewals of approved projects, approval of protocol amendments, research conducting health record review, and for confirming changes required by the ethics committee for approval of the protocol.

External/Independent Consultant - an expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols; with no affiliation to the institute(s) or investigator(s) proposing the research proposal.

Full board review - review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting

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Good clinical practice guidelines (GCP) - an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible. These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are properly documented. For complete information, reference is made to the published WHO and International Conference on Harmonization Code of Good Clinical Practice. (Department of Health Administrative Order No. 47-A series of 2001, [August 30, 2001]; It is a standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical products (diagnostic, therapeutic or prophylactic) under investigation are properly documented (World Health Organization, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

Guidelines - a set of rules or recommendations intended to effect a course of action.

High Risk - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution. The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.

Human participant or subject - human participant means a living individual about whom a Researcher conducting research obtains data through intervention or interaction with the individual, or identifiable private information, or an equivalent definition.

Informed consent - the process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making; It is "a decision to participate in research, taken by a competent

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individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation” (CIOMS, 2002).

Informed Consent Document/Form - a document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Institutional Ethics Review Committee (IERC) - the committee in St. Luke’s Medical Center responsible for the review of the protocols of all sponsor-initiated clinical trials (SiT) and IiT involving human subjects to ensure that the studies adhere to the ethical standards of the International Conference of Harmonization Guidelines for Good Clinical Practice (ICH-GCP), the Philippine Health Research Ethics Board (PHREB), and other standards and guidelines on ethics in research (i.e. Declaration of Helsinki, Philippines National Ethical Guidelines for Health Research). *See also ethics review committee, research ethics committee.*

Institutional Scientific Review Committee (ISRC) - the committee in St. Luke’s Medical Center responsible for reviewing the technical soundness and scientific validity of the protocols of all investigator-initiated clinical trials and research projects (IiT), whether SLMC-funded or externally-funded.

Investigational product - a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. [ICH-GCP E6(R2), 2016]

Investigator - a person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6, R1); It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and

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other credentials. Decisions relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products); The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site or group of sites *See also principal investigator.*

Investigator's Brochure - a compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects. [ICH-GCP E6(R2), 2016]

Legally Acceptable Representative (LAR) - an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial. [ICH-GCP E6(R2), 2016]

Minimal risk - if the consequences can be dealt with by routine operations the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

Moderate Risk - risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.

Monitor - a person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

Monitoring - the process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or research and/or to check researcher's compliance with the protocol and regulatory requirements with in which the protocol is given ethical approval. *See also clinical research monitoring.*

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Office of Research Integrity (ORI) - an office under the St. Luke's Medical Center Research and Biotechnology tasked with the following responsibilities and functions: (1) establishment and promotion of the code of ethical professional behavior in the conduct of human, animal, and basic science research in SLMC through the development, evaluation and revision of policies, procedures and regulations related to the responsible conduct of research and the prevention of research misconduct; (2) communication within SLMC, external research partners, collaborators, Sponsors of CTs/research projects, Contract Research Organizations (CROs), Academic Research organizations (AROs) and patients, its commitment to protect human research participants and support the code of ethical professional behavior; (3) maintaining the development of and compliance with all human research policies and procedures; (4) protection of patients enrolled in research irrespective of the sponsor of the research; (5) provision of support to the structure and operational requirements of the research review function to ensure that all research studies conducted in SLMC and SLMCCM-WHQM are epidemiologically valid, correctly conducted and conform to acceptable quality standards and ethics in research; (6) ensuring that the review function complies with applicable laws and regulations; (7) annual review of all research review processes; (8) detection and investigation of research misconduct; (9) recommending administrative action for research misconduct findings; and (10) implementing education and training activities to teach the responsible conduct of research.

Philippine Health Research Ethics Board (PHREB) - the policy-making body for research ethics in the Philippines created on March 1, 2006 through DOST Special Order No. 091 series of 2006.

Principal Investigator - the chief or person primarily responsible for the implementation of a research project. *See also investigator, project leader*

Privacy - the right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively; It is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others.

Project Leader - the primary person responsible for the conceptualization and implementation of a research project involving humans.

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Protocol - a document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22);

- A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. [ICH-GCP E6(R2), 2016]

Protocol amendment - a written description of a change(s) to, or formal clarification of a protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22) *See also amendment to the protocol.*

Protocol deviation - a minor or administrative departure from the IRB- approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior IRB approval. It is an accidental or unintentional change to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of the Principal Investigator or the Clinical Trial staff.

Protocol violation - an accidental or unintentional change to, or non-compliance with the IRB approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) without prior IRB approval. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.

Quorum - at least five people, including at least one lay member and one non-affiliated member, are present to make decisions about the proposed research (WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011).

Regulatory requirements - necessary prerequisites for the approval and conduct of clinical trial by a national regulatory authority. For example, for pharmaceutical and biologic products it means

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obtaining a “permit for clinical investigational use” which is a “registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country” DOH Administrative Order No. 47-A series of 2001”Rules and Regulations on the registration including approval and conduct of clinical trials, and lot or batch release certification of vaccines and biologic products.” See Permit for clinical investigational use.

Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or an equivalent definition.

Research ethics committee (REC) - an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. [ICH-GCP E6(R2), 2016] See also *Institutional Ethics Review Committee, ethics review committee*.

Research participant or subject - an individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22)

Research protocol - a document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. See also *protocol*.

Risk - the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be



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justified by the anticipated benefits to the subjects or to society. The investigator(s) and IRB must assess the risks and benefits of proposed research. *See also minimal risk.*

Risk-benefit ratio - the risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated. (clinicaltrial.gov/ct2/info/glossary)

Risk factors - variables or conditions that increase the risk or chances of disease or infection; determinants of disease development. *See also risk.*

Serious adverse event (SAE) - any adverse drug experience occurring at any dose that results in any of the following outcomes: Death; Life-threatening drug experience; In-patient hospitalization or prolongation of existing hospitalization; Persistent or significant disability or incapacity; and Congenital anomaly/birth defect. (21 CFR 312.32)

- Important medical events that may not result in death, be life-threatening or require hospitalization but when based upon appropriate judgment may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes mentioned above.

Sponsor - an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Study document - all records, accounts, notes, report, data and ethics communications (submission, approval and progress reports) collected, generated or used in connection with the Study, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and construction of the Study.

Suspected unexpected serious adverse reaction (SUSAR) - any adverse drug experience the specificity or severity of which is not consistent with the current Investigator Brochure or with the risk information described in the general investigational plan or elsewhere in the current application. "Unexpected" as used in this definition refers to an adverse drug experience that has not been previously observed or from the perspective of the pharmacological properties of the test product is not anticipated.



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Voluntary - free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. (IRB Guidebook, USDHHS in http://www.hhs.gov/ohrp/irb/irb_glossary.htm downloaded on June 19, 2010)

Vulnerability - a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, General Ethical Principles)

Vulnerable persons/groups - individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. [ICH-GCP E6(R2), 2016]

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, Commentary on Guideline 9).

These are also classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare. These are "persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority" (<http://www.pre.ethics.gc.ca/english/tutorial/glossary.cfm#c> down loaded on July 9, 2010)

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8. REFERENCES

- This Manual addresses the Human Subject Research Program (HRP) of the Joint Commission International (JCI)
- Policies on:
 - Institutional Ethics Review Committee, Research 1-06-7 (April 1, 2025)
 - Functional Group Policy (Research and Biotechnology), Leadership 1-113-6 (April 1, 2025)
 - Clinical Trials and Research Projects, Research 1-02-9 (January 30, 2025)
 - Clinical Research Monitoring, Research 1-03-5 (February 7, 2025)
 - Monitoring of Clinical Safety of Investigational Drugs, Research 1-04-3 (January 6, 2025)
(Refer to the SLMC policies and procedures page to access the recent versions of the related documents)
- Association for the Accreditation of Human Research Protection Programs, Inc. (2018). Evaluation Instrument for Accreditation. Washington, DC: Association for the Accreditation of Human Research Protection Programs, Inc.
- Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.
- Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences.
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- National Ethics Committee Standard Operating Procedures, version 2 (2015). Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.
- Philippine Health Research Ethics Board. (2020). Standard Operating Procedures Workbook for Ethics Review Committees. PHREB.



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- Philippine Health Research Ethics Board. (2022). National Ethical Guidelines for Research Involving Human Participants. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.
- Republic of the Philippines (2013). Republic Act No. 10532 - Philippine National Health Research System Act of 2013. Manila: Republic of the Philippines.
- Republic of the Philippines. (2012). Republic Act No. 10173 - Data Privacy Act of 2012. Manila: Republic of the Philippines.
- World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.
- World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.
- World Health Organization. (2020). Guidance for research ethics committees for rapid review of research during public health emergencies. Geneva: World Health Organization.
- World Medical Association. (2024). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.
- Joint Commission International. (January 1, 2025). Joint Commission International Accreditation Standards for Hospitals: Including Standards for Academic Medical Center Hospitals (8th Edition). Joint Commission Resources.